WAR ROOM / DAILYCLOUT

PFIZER DOCUMENTS ANALYSIS REPORTS

Find Out What Pfizer, FDA Tried to Conceal

PFIZER DOCUMENTS INVESTIGATIONS TEAM

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EDITED BY DAILYCLOUT

Foreword

The following book represents an extraordinary historical achievement in the reporting of events in science and medicine.

It also appears to be a record of a great crime against humanity.

In 2022, the Pfizer documents, a tranche of 55,000 documents, many of them thousands of pages long, were released via a court order. This was due to a successful lawsuit by attorney Aaron Siri. The US Food and Drug Administration had asked the court to keep these documents hidden for 75 years — until after most of us alive now would be dead and gone.

Luckily, the court did not concur.

We at DailyClout.io, a website devoted to civic transparency, realized that the raw documents were impossible to cover in normal journalistic ways. One reason was the massive scope of the documentation. But another reason was that the documents are written for scientists and medical researchers, in language that only specialists in those fields could really understand properly or explain.
We sent out a call for expert volunteers from those fields on our own platforms, and we did so also on the video and podcast platform, War Room Pandemic, hosted by Stephen K. Bannon. A global audience thus recognized how important it was for an informed public — who had been harried, bullied, and "mandated" to receive Pfizer's and Moderna's mRNA injections in 2021-2022 — to understand what was really revealed inside of the Pfizer documents.

As a result of our calls for expert help, we received 2000, then 2500, and finally 3500 responses from volunteers, many of whom are experts in their fields. Biostatisticians, lab clinicians, pathologists, anesthesiologists, sports medicine physicians, cardiologists, research scientists, RNs, and many other related disciplines are represented among these decent, highly-skilled people who offered to read through these difficult, technical documents — pro bono, as a service to humanity (and out of respect as well, in many cases, for their own lifelong commitment to real science, real medicine, and truth in general). Many of them were not only published, peer-reviewed academic authors in their fields, but some were peer reviewers themselves. There was no way, with a group this distinguished in science and medicine doing the labor, that the interpretation of these documents could be dismissed as "fringe," subjective, or as the work of "conspiracy theorists."

Of course, managing a project in which 3500 highly trained specialists from all over the world work together virtually on unpacking and reporting on such a massive trove of material, would have been impossible for mere mortals.

At first, indeed, we did not know how to organize the thousands of specialists who offered their help. Enter Amy Kelly, who is also the heroine of this story. She is a talented project manager, and now DailyClout's COO; and she has a distinguished background in complex organizational projects in various fields.

Ms. Kelly managed, seemingly effortlessly, to organize the volunteers into six working teams, with subcommittees of expert readers. Under her extraordinary leadership, thousands of specialists around the globe started to communicate with one another, share their findings, and draft their reports. I trained the volunteers in writing for a general audience, and I also trained our DailyClout editors in editing what was often dense medical language, but with extremely important findings, into accessible reports that anyone with any level of education could follow and understand.

For all of us, but mostly for the volunteers and Ms. Kelly, the next year represented a Herculean effort to turn this material, that one of the most powerful companies in the world trusted would never be made public, into fifty readable reports sharing the most urgent headlines of all — the reports that are now in your hands.

You will see that the 46 reports document what may be a massive crime against humanity. You will see that Pfizer knew, as it appears, that the mRNA vaccines did not work. You will see that the ingredients, including lipid nanoparticles, in the mRNA injections bio-distributed throughout the body in a couple of days, accumulating in the liver, adrenals, spleen — and ovaries. You will see that Pfizer and the FDA knew that the injections damaged the hearts of minors — and yet waited months to inform the public. You will see that Pfizer sought to hire over a thousand new staffers simply to manage the flood of "adverse events" reports that they were receiving and that they anticipated receiving. You will see that 61 people died of stroke — half of the stroke adverse events being within a couple of days after injection — and that five people died of liver damage with, again, many of the liver damage adverse events sustained shortly after the injection. You will see neurological events, cardiac events, strokes, brain hemorrhages, and blood clots, lung clots and leg clots at massive scale. You will see that headaches, joint pain, and muscle pain are rampant as adverse events, though these are not disclosed as routine side effect warnings by our agencies.

Most seriously of all, you will see a 360-degree attack on human reproductive capability: with harms to sperm count, testes, sperm motility; harms to ovaries, menstrual cycles, placentas; you will see that over 80 per cent of the pregnancies in one section of the Pfizer documents ended in spontaneous abortion or miscarriage. You will see that 72 per cent of the adverse events in one section of the documents were in women, and that 16 percent of those were "reproductive disorders," in Pfizer's own words. You will see a dozen or more names for the ruination of the menstrual cycles of women and teenage girls. You will see that Pfizer defined "exposure" to the mRNA vaccine as including skin contact, inhalation and sexual contact, especially at the point of conception.

History has not yet concluded its assessment of what Pfizer — and the FDA, who were in custody of all of these documents — has done. We are at the very start of that assessment.
But to me it is clear that the following documents, written by impeccably skilled experts, and linked to primary sources, show that a crime has likely been committed against humanity that is unprecedented in its scale.

We owe the War Room/DailyClout Pfizer Documents Research Volunteers — some named, most of them unnamed — who labored for a year, and do so to this day, and for nothing more than the privilege of serving humanity, science, medicine and the actual truth — a tremendous debt. We thank Mr. Bannon and his team for so often supporting our call for experts and for helping us to announce the results in real time, as the reports came in. We thank all of the other news outlets, of all kinds, who risked reprisals from Big Pharma or even from the government — which recent lawsuits have shown allied with Big Pharma — who have also showcased the work of the Volunteers, in an effort truly to inform their viewers.

Please share this document with your loved ones if you also find it to be important.

Everyone by law deserves informed consent when it comes to medical interventions — it is actually a crime to withhold it (really many crimes appear to be represented here, but history will sort that out as well).

It has been a privilege to report on this team's work, and to do all I can as CEO of DailyClout, to help sustain their, and the remarkable Ms. Kelly's, work on humanity's behalf.

Sincerely,

Dr. Naomi Wolf
CEO, DailyClout.io
January 20, 2023
Salem, Massachusetts

War Room/DailyClout
Pfizer Documents Analysis
Volunteers' Reports

For the children and grandchildren.

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Summary

The Top Sixteen Major Concerns from the FDA's Pfizer Documents Release Through August 24, 2022 – Written by Louisa Clary, Lisa Laehy, and Pierre Kory, MD.

BACKGROUND

The Food and Drug Administration (FDA) asked a federal court to allow them 75 years to publicly release Pfizer's COVID-19 vaccine data submitted to the agency.

The court ordered the FDA to immediately begin releasing 55,000 pages of the Pfizer vaccine data per month into the public domain.

This report draws from the original analysis of the War Room/DailyClout team of over 3,000 expert volunteers who analyzed the documents released to date, including:

- Pfizer's COVID-19 vaccine clinical trial data
- Pfizer's real-world data during the first 12 weeks of its Covid-19 vaccine roll-out from December 1, 2020, through February 28, 2021

EFFICACY

ONE:

Pfizer's claim of 95% efficacy was based on only a tiny number of COVID-19 cases in the clinical trials – 170 cases in over 40,000 trial participants. A measure of vaccine efficacy among such a small sample of COVID-19 cases is too insignificant to generalize to hundreds of millions of people in the population.

- When comparing the number of participants who showed antibody evidence of having contracted COVID-19 during the trial, only a 54% efficacy in protection is found.

- Since vaccine recipients often do not make viral antibodies despite having contracted COVID-19, an even greater number of vaccine recipients who became infected during the trial were not counted and the actual efficacy was far less than 50% – yet the FDA still issued an EUA.

TWO:

Pfizer's clinical trial data showing strong safety and efficacy conflict with Pfizer's real-world data submitted to the FDA. Of the 32,760 injured vaccine recipients with known outcomes during the first 12 weeks of the vaccine roll-out, Pfizer reported:

- Approximately 20% of the reports involved COVID-19 illness
- COVID-19 was the third most frequently reported adverse event
- Over 15% of the COVID-19 cases were graded as severe
- Over 200 people in this post-marketing study died from COVID-19

SAFETY

THREE:

Contrary to public statements by Pfizer and FDA, both were aware of data showing that the vaccine ingredients travel from the injection site through the bloodstream, cross important blood-organ barriers (including at the brain, testes, and ovaries), and continue to produce harmful spike proteins for an undetermined amount of time.

FOUR:

Pfizer did not expect more than 158,000 separate adverse events to be reported during the initial 12-week rollout and had to hire a small army of 2,400 *additional,* full-time staff to manage the case load.

Despite these additional staff, Pfizer could not determine the outcome in over 20,000 people reporting vaccine injuries.

FIVE:

As Pfizer tracked adverse events during the first 12 weeks of the vaccine rollout, 270 pregnant women reported a vaccine injury, but Pfizer only followed 32 of them and 28 of their babies died. This is a shocking 87.5% fetal death rate.

SIX:

Pfizer's real-world data demonstrated a range of adverse side effects for breast-feeding mothers who received the vaccine and for their nursing babies, including infantile vomiting, fever, rash, agitation,

and allergy to the vaccine; in addition, breast-feeding mothers experienced partial paralysis, suppressed lactation, breast pain, migraines, and breast milk discoloration to a blue/green color.

Ignoring this alarming data on vaccination during pregnancy and nursing, Pfizer, the federal health agencies, and numerous medical societies strongly recommended that pregnant and nursing women across the country receive the mRNA vaccines.

SEVEN:

Pfizer's clinical trial documents suggest that its mRNA vaccine ingredient that instructs for spike protein can be transferred from one person to another by skin-to-skin contact, inhalation, and by sexual intercourse through bodily fluids, causing an unvaccinated person to have an "environmental exposure" to the vaccine. In other words, "shedding" is a real concern expressed in Pfizer's own documents. Yet as late as July 2022, the Centers for Disease Control and Prevention (CDC) assured Americans that COVID-19 mRNA vaccine shedding is a "myth" and is "misinformation."

EIGHT:

The Pfizer study inclusion criteria for men requiring either total abstinence from sex with women of childbearing age, or the use of both condoms and other "highly effective" contraception, and to refrain from donating sperm, suggest that Pfizer suspected that vaccinated men's ejaculate could affect both women and unborn children conceived during the trial and afterward.

NINE:

Pfizer did not evaluate vaccine adverse effects on male fertility during clinical trials because the company was in a rush, stating that the absence of reproductive toxicity data was necessary to speed its vaccine development and meet the allegedly urgent health need. Yet Pfizer's trial documents show that the company knew its vaccine ingredients (the lipid nanoparticles carrying the mRNA) pass the blood-testicular barrier and that previous studies had shown that nanoparticles accumulate in the testes and cause reproductive harm by adversely affecting sperm quality, quantity, morphology, and motility.

TEN:

During Pfizer's study of vaccine adverse events during the public rollout in early 2021, Pfizer included "anti-sperm antibody positive" among its 1,290 adverse events of special interest that were reported. The presence of anti-sperm antibodies in male ejaculate is an immune cause of male infertility, as adhesion of antibodies to sperm affects their motility (movement), making the sperm's journey to the egg highly difficult or even impossible.

ELEVEN:

Although mRNA occurs naturally in the body and degrades quickly, Pfizer modified the vaccine RNA (modRNA) so that (i) it continues making spike proteins for an untested duration, (ii) it produces more numerous spike proteins in untested amounts, and (iii) it disables the body's normal immune reactions which may suppress immunity to other diseases such as viruses and cancer. Despite such significant modifications to the vaccine mRNA, Pfizer did not perform the normal studies measuring duration of the mRNA or spike proteins, or the doses of spike proteins produced by modRNA in different individuals.

TWELVE:

During the vaccine rollout in early 2021, cases of myo-pericarditis (inflammation of the heart lining and muscle) were reported to Pfizer, and one month before the EUA for teens was granted (May 2021), a peer-reviewed study showed that 35 teenagers had suffered myocarditis after their Pfizer vaccines. In August 2021, after millions of teens had received the vaccine, FDA, CDC, and Pfizer issued the warning about myocarditis risk in teens.

THIRTEEN:

Pfizer did not disclose that its COVID-19 vaccine ingredients include micro-RNAs (miRNAs), which are an important natural component of gene expression and regulation and are associated with many diseases as well as a person's immunity. miRNAs coming from outside the body such as in Pfizer's vaccine alter the delicate balance among these naturally occurring molecules, with the potential for harmful health consequences that Pfizer has not studied.

FOURTEEN:

Pfizer's Phase 3 trial in humans was supposed to compare the vaccine group against the control group receiving the placebo for two full years in order to measure the safety of the vaccine, but Pfizer eliminated most of the control group after four months by vaccinating those who had received the placebo injection. This removes the vital opportunity for measuring whether the vaccines are causally connected with other poor health conditions that develop after vaccination.

FIFTEEN:

The Pfizer documents raise serious concerns about the manufacturing standards for the vaccine: the FDA criticized the Kansas facility packaging the mRNA vaccine ingredients in 2019 and 2020 for

”mold and bacteria, and drugs released without quality inspection,” and as of the latest inspection, Pfizer continues to recover bacterial and/or mold isolates from critical zones, according to the FDA.

SIXTEEN:

In September 2021, Pfizer and the FDA did a bait-and-switch by licensing a version of Pfizer’s vaccine, called Comirnaty, and although they claimed that Pfizer’s emergency use (EUA) version was “interchangeable/equivalent” with Comirnaty, Pfizer documents show that only approximately 4% of the EUA vaccine was interchangeable and was not available to the general public. Pfizer states, *“Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with [Comirnaty]”* – exactly 9 out of 190 total lots.

Pfizer’s favorable clinical trial conclusions contradict the real-world adverse effects and efficacy failures documented after the public rollout of Pfizer’s COVID vaccine.

If Pfizer had a TV commercial for its Covid vaccine listing the 158,893 adverse events reported in the first 12 weeks, the announcer would be reading them for more than 80 consecutive hours.

References:

- Summary of Efficacy Clinical Trials (Pfizer Summary of Clinical Efficacy (Table 5 Page 36, DCS, pp. 50-59)
- Nonclinical Overview (Immunogenicity, PK, and PD) https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf
- Pfizer Biodistribution - Japanese Luciferase study - https://www.naturalnews.com/files/Pfizer-bio-distribution-confidential-document-translated-to-english.pdf

- https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p. 24.
- Pfizer Post-Marketing Experience - Adverse Events After Public Rollout (12/1/20 - 2/28/21) (https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf).
- New addition in August, DailyClout Pfizer Documents released July 1 - https://dailyclout.io/pfizer-misleadingly-classified-the-44-percent-of-pregnancies-that-ended-in-miscarriage/.
- New release, AUG 2022 - TRIAL PROTOCOL AMENDMENTS, “A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates

Against COVID-19 in Healthy Individuals," Protocol Amendment 14, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, pp. 213, 246, 398, 431, 575, 607, 751, 783, 918, 948, 1073, 1103, 1226, 1255, 1378, 1406, 1522, 1549, 1663, 1688, 1813, 1836, 1949, 1969, 2081, 2100, 2211, 2228, and 2337.

- Reference: Pfizer Summary of Clinical Efficacy (Table 5 Page 36; DCS, pp. 50-59); and https://philharper.substack.com/p/pfizer-documents-show-pfizer-made (Phil Harper analyzes Pfizer Clinical Efficacy document.)

Report 1: "What Happened to Pfizer's Missing Patients?" – Team 5.

Within this Pfizer post-marketing document (https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf), there appears to be a large number of "not recovered at the time of report" and "unknown" case outcomes. As shown in Table 1, these numbers are significant, adding up to 20,761 out of 42,086 "relevant cases." Do we know what happened to them? Has this large number of unknown outcomes and patients who had not recovered at the time of this report been reported anywhere in the press, on the HHS.gov website (FDA, CDC, etc.), or on the Pfizer main website? This number dwarfs the reported deaths number so finding out the eventual outcome is vitally important.

What Happened to Pfizer's Missing Patients?

A great deal of data are missing from Pfizer's analysis of adverse events that were reported after the Pfizer mRNA vaccine was approved by the US Food and Drug Administration ("5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021," https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). From the data that are provided, many more questions arise.

- Of the 42,086 cases that Pfizer analyzed, 32,686 (78%) have known outcomes. The outcomes of almost one-quarter (22%) are not known (Table 1, p. 7, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). Why are these case reports incomplete?

- Nearly three-quarters (71%) of the 42,086 patients are female; 22% of the patients are male; another 7% have no sex identified (Table 1, p. 7, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). Why are so few male patients included in the Pfizer report? This is especially worrying, since the Centers for Disease Control states that it is in male adolescents and young adults that most cases of myocarditis and pericarditis have been reported (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html). Does this explain why Pfizer does not include myocarditis or pericarditis among the cardiovascular adverse events (Table 7, p. 16, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf)? Instead, Pfizer buried the myocarditis and pericarditis cases in its review of immune-mediated/autoimmune adverse events (Table 7, p. 20, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf).

- Sadly, 1,223 (3.7%) of the 32,686 patients with known outcomes died (Table 1, p. 7, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). Thus, in 3.7% of the adverse event cases with known outcomes, the Pfizer mRNA vaccine proved fatal. If we

knew the number of doses that were shipped worldwide, we could determine the actual mortality rate; unfortunately, Pfizer has redacted that information (p. 6, Section 3.1.1, paragraph 1, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). The Centers for Disease Control suggests that the number of deaths should be much less, around 0.003% (paragraph 2, https://www.cdc.gov/mmwr/volumes/71/wr/mm7101a4.htm). What is the actual mortality rate for the injection?

- Four (0.3%) of the 1,223 deaths occurred on the same day the patients received the mRNA vaccine. These patients died of anaphylaxis, although "they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia" (Table 4, footnote b, p. 10, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). Nonetheless, the Centers for Disease Control advises that "staying up to date with COVID-19 vaccines (getting primary series and booster) . . . is especially important if you are older or have severe health conditions or more than one health condition . . ." (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html). Is this advice consistent with the deaths from anaphylaxis?

- Pfizer's 3.7% fatality rate for the adverse event cases with known outcomes doesn't include patients that Pfizer said had not recovered at the time of the report (30 April 2021). Of the 32,686 patients with known outcomes, 11,361 (35%) of the patients are listed as not recovered (Table 1, p. 7, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). Did those 11,361 patients survive the Pfizer mRNA vaccine?

- Of the 32,686 patients with known outcomes, 19,582 (60%) of the patients are lumped together as recovered/recovering (Table 1, p. 7, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). We can assume that recovered cases are free from residual adverse events, but what was the outcome of recovering cases—did they ultimately get well? In reality, recovered and recovering cases should not be combined; instead, coupling not recovered and recovering cases is a more honest way to present the data. By combining recovered and recovering cases, is Pfizer attempting to overcount the number of cases in which the adverse events were resolved?

- Clearly, patients who received the mRNA vaccine weren't adequately tracked, possibly because of the way the mRNA vaccine was named. Pfizer requested a waiver of the standard method for assigning a unique name to the vaccine (p. 4, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M1_waiver-req-designated-suffix.pdf). The purpose of the unique name is to "secure pharmacovigilance so that the FDA can effectively monitor all biological products in the post market" and to "aid in adverse event report tracking" (paragraph 5, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-steps-naming-biological-medicines-balance). Pfizer's waiver request notes that

the standard naming method "would be burdensome and redundant" (p. 3, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M1_waiver-req-designated-suffix.pdf). Did Pfizer request the waiver knowing it would be more difficult to track and report adverse events experienced by patients?

Pfizer's report raises more questions than it answers. Yet in Pfizer's review of adverse events reported after the Pfizer mRNA vaccine was approved by the FDA, they conclude that their review "confirms a favorable benefit:risk balance" for the mRNA vaccine (p. 29, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). With 22% of patients having unknown outcomes, 35% not recovered at the time of the review, and 3.7% dead, Pfizer concludes that the benefits of taking their mRNA vaccine outweigh the risks. So another question arises: how can that conclusion be true?

Even without knowing what happened to the missing patients, the data in Pfizer's analysis of adverse events raise important warning flags. Consider the absolute number of major adverse cardiac events that Pfizer reviewed. In the period from 24 hours to 21 days after receiving Pfizer's mRNA vaccine, there were 394 total cases that included the following.

- Arrhythmia: 102 cases
- Myocardial infarction: 89 cases
- Acute myocardial infarction: 41 cases
- Cardiac failure: 80 cases
- Acute cardiac failure: 11 cases
- Cardiogenic shock: 7 cases
- Orthostatic tachycardia syndrome: 7
- Pericarditis: 32 cases
- Myocarditis: 25 cases

Are nearly 400 major adverse cardiac events enough to pause or stop the widespread use of Pfizer's mRNA vaccine?

Report 2: "136 Deaths and 1,625 Serious Case of 'Ineffectiveness' Revealed." Vicki Goldstein, RN, JD – Team 1.

Astonishingly, Pfizer's internal documents that were recently released by court order revealed that beginning on December 1, 2020, Pfizer was aware that the vaccine that was pushed upon the American people had limited efficacy.

For the next 3 months, from 12/1/2020-2/28/2021, Pfizer's 5.3.6 cumulative analysis of post authorization adverse events reports indicate that Pfizer received multiple reports of both vaccine failure and vaccine ineffectiveness.

According to Pfizer's cumulative analysis, there were 16 serious cases of vaccine failure and 1,625 serious cases of vaccine ineffectiveness reported. (Page 14). In the same Pfizer document, Covid-19 is identified as an adverse event special interest (AESI), with 3,067 cases of Covid-19 reported after receiving the vaccine. From that number, there were 2,585 serious relevant events, including Covid pneumonia, and 136 people died. (Page 17)

Pfizer excluded cases from analysis, including 546 cases in which SARS-CoV-2 infection was developed between days 1-13 from the first dose. (Page 15). After allowing for Pfizer's exclusion of some cases, this data still reveals multiple serious cases, including fatalities, indicating there is vaccine failure and vaccine ineffectiveness with Pfizer's vaccine. And worse, Pfizer, which is responsible for the post authorization analysis, admits that there are limitations in the reporting and that "the magnitude of underreporting is unknown." (Page 5).

Even though there were multiple reports of lack of vaccine efficacy, Pfizer stated in the confidential document that "no new safety signals of vaccine lack of efficacy have emerged based on a review of these cases." (Page 15)

However, just as Dr. Fauci anticipated in 2020, the duration of vaccine protection is limited. Dr. Fauci stated that "if Covid-19 acts like other coronaviruses, it likely isn't going to be a long duration of immunity," (https://www.cnbc.com/2020/06/02/dr-anthony-fauci-says-theres-a-chance-coronavirus-vaccine-may-not-provide-immunity-for-very-long.html)

Dr. Fauci told Dr. Collins in 2020 regarding the Covid vaccines that "we're going to assume that there's a degree of protection, but we have to assume that it's going to be finite. It's not going to be like a measles vaccine. So, there's going to be follow-up in those cases to see if we need a boost. We may need a boost to continue the protection." (Excerpts from NIH Director Dr. Collins's conversation with NIAID Director Dr. Fauci, https://newsinhealth.nih.gov/2020/08/dr-anthony-fauci-covid-19-vaccines)

The findings from a Swedish study from 12/28/2020 to 10/4/2021 "show there was a progressive waning of vaccine effectiveness of BNT162b2 (Pfizer) against SARS-CoV-2 infection of any severity, with no vaccine effectiveness detected from 7 months onwards."
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00089-7/fulltext

The study found that "**unlike natural immunity, which appears robust with little waning for a year following infection**, there is a gradual but relatively rapid waning in vaccine immunity against infection following the second dose." https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00277-X/fulltext?rss%3Dyes (emphasis added)

"Waning immunity (is) also known as secondary vaccine failure". Israel attributed an increase in infections and hospitalizations of vaccinated persons due to a "combination of waning vaccine immunity… and from potentially reduced effectiveness of the (Pfizer) vaccine against the delta variant."
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02249-2/fulltext

A report from the FDA indicates that the efficacy of Pfizer's vaccine wanes. Immunogenicity (measures how well a vaccine is working) of the original strain of SARS-CoV2, was identified in a study as follows:
Neutralizing antibody titers against original strain: **762** 1 month post-second dose.
Neutralizing antibody titers decreased to **136** prior to first booster.
The antibody titers increased to **2374.2** 1 month post-booster
https://www.fda.gov/media/152239/download

Now there are reports that the efficacy of the booster is waning after 3-6 months.
"Emerging evidence, including data from Kaiser Permanente Southern California (KPSC), suggests that effectiveness against both symptomatic COVID-19 and severe disease caused by Omicron wanes 3 to 6 months after receipt of an initial booster (third dose). Thus, additional booster doses may be needed to ensure individuals remain adequately protected." https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-submit-us-emergency-use-authorization

On March 15, 2022, Pfizer submitted an application for EUA of an additional booster dose for older adults who have received an initial booster. On March 29, 2022, the FDA authorized a second Pfizer Covid-19 vaccine booster in persons aged 50 years and older in addition to immunocompromised persons aged 12 years and older.

In support of yet another booster, Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research (CBER), stated that **"current evidence suggests some waning of protection over time against serious outcomes from Covid-19….and a second booster dose…. could help increase protection levels for …higher-risk individuals." (**emphasis original) https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and

There is an abundance of evidence that the Pfizer vaccine has a serious durability problem, resulting in waning protection and vaccine failure.

In a risk/benefit analysis, the risk of known serious adverse events, including death, from the vaccine, outweighs the possible benefit of a vaccine that we know will fail.

The vaccine program must stop. We need to focus on early treatment and natural immunity.

Report 3: "Phase 1 /2 Study of COVID-19 RNA Vaccine BNT162b1 in Adults: Key Processes Missing." – Robert W. Chandler, MD, MBA – Team 5.

Phase 1 / 2 study of Covid-19 RNA vaccine BNT162b1 in Adults
Mulligan, Lyke et al. Nature Published online 8/12/2020.

> Cite this article as: Mulligan, M. J. et al.
> Phase 1/2 study of COVID-19 RNA vaccine
> BNT162b1 in adults. Nature https://doi.
> org/10.1038/s41586-020-2639-4 (2020).

P1 p2: The authors' put forth the argument that mRNA in BNT162b1 (Note this series used **BNT162b1** not **BNT162b2**) briefly expresses the encoded protein and then is metabolized without being incorporated into the host genome.

"RNA is required for protein synthesis, **does not integrate into the genome, is transiently expressed, and is metabolized and is eliminated by the body's natural mechanisms and, therefore is considered safe.**"[4, 7]

> [4]*Alberer, M. et al. Safety and immunogenicity of a mRNA rabies vaccine in healthy adults: an open-label, non-randomized, prospective, first-in-human phase 1 clinical trial. Lancet 90, 1511-1520 (2017).*
>
> [7]*Sahin, U. e al. Personalized RNA mutanome vaccines mobilize poly-specific therapeutic immunity against cancer. Nature 547, 222-226 (2017).*

However, Zhang et al. working at MIT demonstrated fragments of SARS-CoV-2 integrated in host DNA in a paper published in 2021, *PNAS* vol. 118, no. 21.

> It will be important, in follow-up studies, to demonstrate the presence of SARS-CoV-2 sequences integrated into the host genome in patient tissues. However, this will be technically challenging because **only a small fraction of cells in any patient tissues are expected to be positive for viral sequences** (61). Consistent with this notion, it has been estimated that only between 1 in 1,000 and 1 in 100,000 mouse cells infected with LCMV either in culture or in the animal carried viral DNA copies integrated into the genome (30). In addition, only a fraction of patients may carry SARS-CoV-2 sequences integrated in the DNA of some cells. However, **with more than 140 million humans infected with SARS-CoV-2 worldwide (as of April 2021), even a rare event could be of significant clinical relevance.** It is also challenging to estimate the frequency of retro-
> integration events in cell culture assays since infected cells usually die and are lost before sample collection. For the same reason, no clonal expansion of integrated cells is expected in

> acute infection experiments. Moreover, **the chance of integration at the same genomic locus in different patients/tissues may be low, due to a random integration process.**

Alden, et al. reporting in *Current Issues in Molecular Biology* 2022, 44, 1115-1126 found BNT162b2 mRNA is reverse transcribed into host DNA beginning 6 hours after contact with BNT162b2.

> In the BNT162b2 toxicity report, no genotoxicity nor carcinogenicity studies have been provided [26]. Our study shows that BNT162b2 can be reverse transcribed to DNA in liver cell line Huh7, and **this may give rise to the concern if BNT162b2-derived DNA may be integrated into the host genome and affect the integrity of genomic DNA, which may potentially mediate genotoxic side effects**. **At this stage, we do not know if DNA reverse transcribed from BNT162b2 is integrated into the cell genome.** Further studies are needed to demonstrate the effect of BNT162b2 on genomic integrity, including whole genome sequencing of cells exposed to BNT162b2, as well as tissues from human subjects who received BNT162b2 vaccination.

Other studies have shown mRNA from BNT162b2 circulates then may reside longer in host cells. This enhanced stability is the result of N1-methyl-Pseudouridine incorporation into the mRNA.

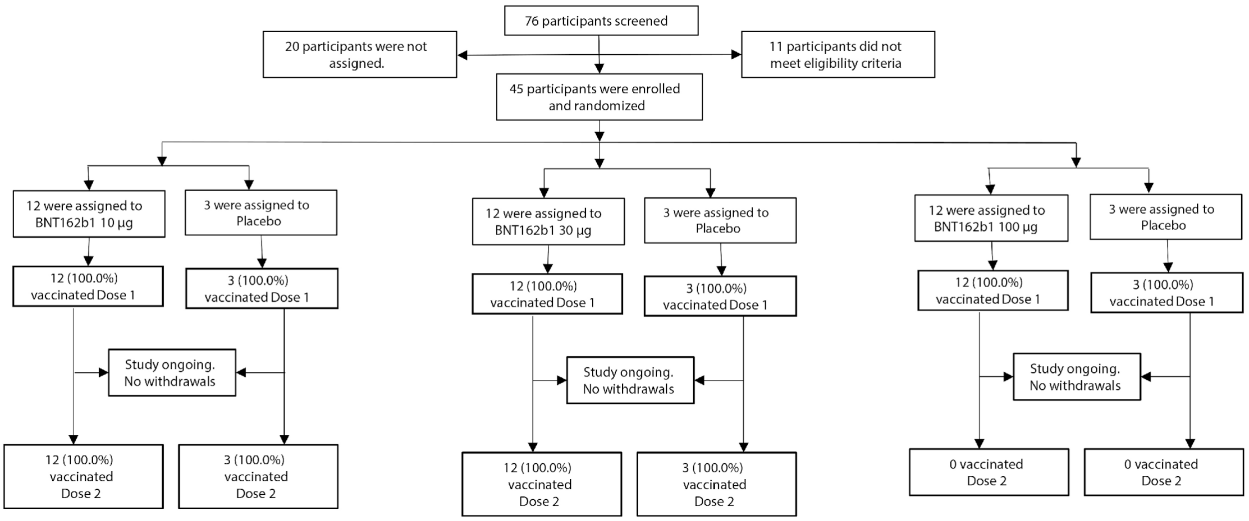
In 2009, Kariko et al. reported that addition of N1-methyl-Pseudouridine to mRNA "...not only suppresses RNA-mediated immune activation in vitro and in vivo, but also enhances the translational capacity of the RNA."

> [11]*Kariko, K. et al. Incorporation of pseudouridine into mRNA yields superior nonimmunogenic vector with increased translational capacity and biological stability. Mol. Ther. 16, 1833-1840 (2008).*

P 1 p3: BNT162b1 was formulated to use N1-methyl-Pseudouridine to stabilize and improve translation. "Vaccine RNA can be modified by incorporating N1-methyl-Pseudouridine which dampens innate immune sensing and increases mRNA translation in vivo.[11]"

"Here, we present available data, through 14 days after a second dose in adults 18 to 55 years of age, from an ongoing Phase I/II vaccine study with **BNT162b1,** which is **also enrolling adults 65 to 85 years of age** (Clinical Trials.gov identifier: NCT04368128)." P2 p1.

Study Design:



- 76 participants screened
- 45 healthy participants randomized into three groups of 12 with 3 placebo groups.
- Mean age 35.4 years, 19-85.
- 51% Male, 49% female.
- Dose levels: 10-µg, 30-µ, 100µ **BNT162b1.**

Page 8 p1: "This study was conducted in healthy men and nonpregnant women 18 to 55 years of age to assess the safety, tolerability, and immunogenicity of ascending dose levels of various BNT162 mRNA vaccine candidates. **In the part of the study reported here, assessment of three dose levels (10-µg, 30-µg, or 100-µg) of the BNT162b1 candidate was conducted at two sites in the United States.** This study utilized a sentinel cohort design with progression and dose escalation taking place after review of data from the sentinel cohort at each dose level."

Endpoints:

- Reporting of solicited local reactions,
- Systemic events,
- Use of antipyretic and/or pain medication within 7 days after vaccination,
- AEs and SAEs (available through up to~45 days after Dose 1)
- Proportion of participants with clinical laboratory abnormalities 1 and 7 days after vaccination
- Shifts in laboratory assessments between baseline and 1 and 7 days after Dose 1 and between Dose 2 and 7 days after Dose 2
- SARS-CoV-2 neutralizing GMT,
- SARS CoV-2 RBD-binding IgG GMCs 7 and 21 days after Dose 1 and 7 and 14 days after Dose 2.

“Hematology and chemistry assessments were conducted at screening, 1 and 7 days after Dose 1, and 7 days after Dose 2.” These data are not reported other than “No Grade 1 or greater change in routine clinical laboratory abnormalities were observed for most participants after either of the BNT162b1 vaccinations. Of those with laboratory changes, the largest changes were decreases in lymphocyte count after Dose 1 in 8.3% (1/12), 45.5% (5/11?), and 50.0% (6/12) of 10 µg, 30 µg and 100 µg BNT162b1 recipients, respectively.” P2 p6.

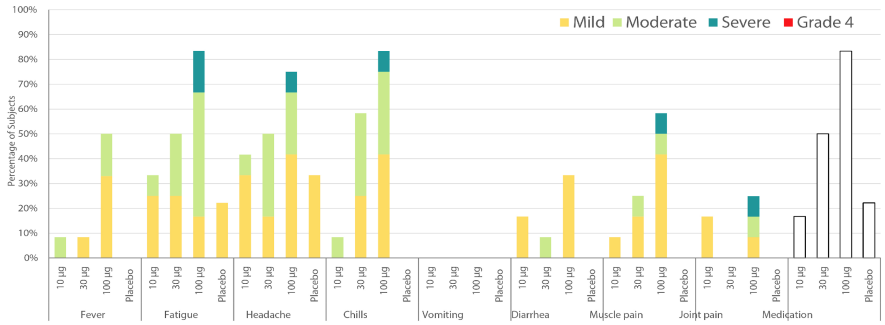
> Upon request, and subject to review, Pfizer will provide the data that support the findings of this study. Subject to certain criteria, conditions, and exceptions, Pfizer may also provide access to the related individual anonymized participant data. See https://www.pfizer.com/science/clinical-trials/trial-data-and-results for more information. These data are interim data from an ongoing study, with the database not locked. Data have not yet been source verified or subjected to standard quality check procedures that would occur at the time of database lock and may therefore be subject to change.

Note: No data such are immediately available on web site 4/6/2022. (see https://www.pfizer.com/science/clinical-trials/trial-data-and-results/data-requests). What studies were performed? Did they measure d-dimer, il-6, troponin, as well as a complete blood count, electrolytes, renal and hepatic function test? Where are the raw data?

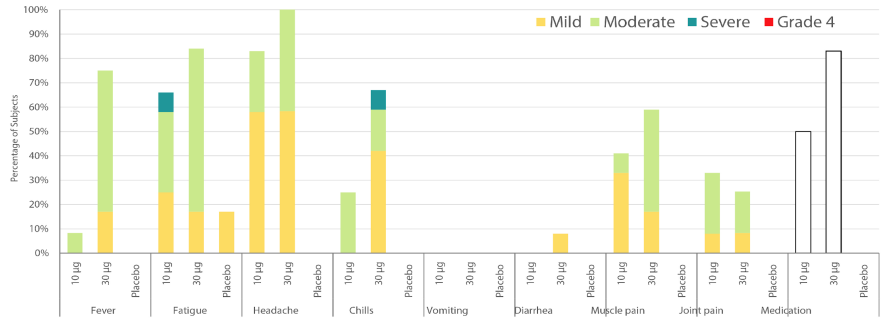
Adverse Event Report:

Figure 3:

Systemic Events Reported within 7 days after Vaccination 1



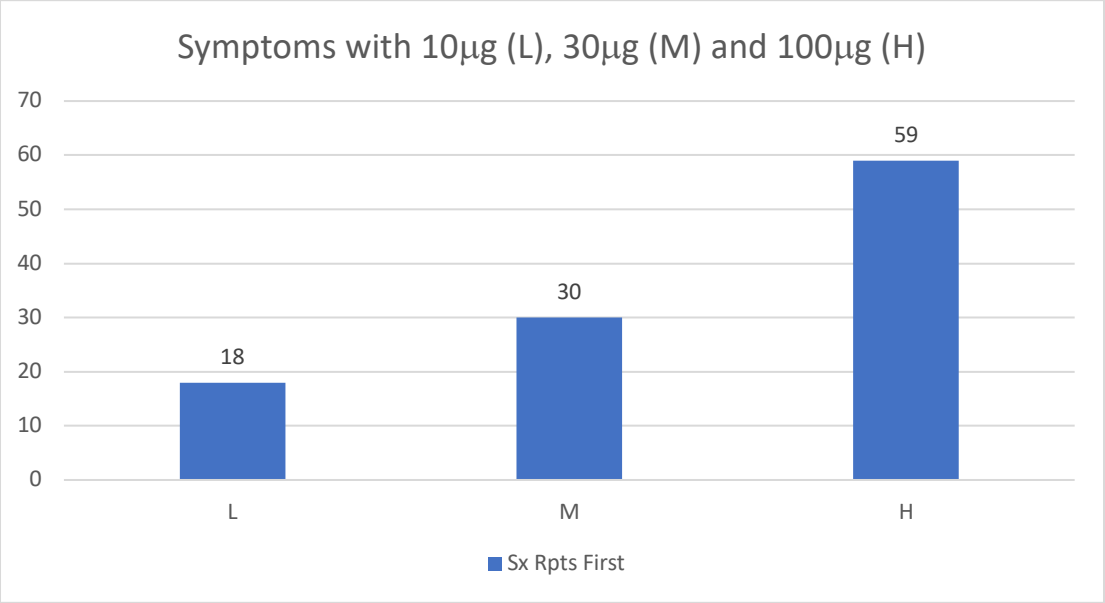
Systemic Events Reported within 7 days after Vaccination 2: 10 µg & 30 µg



In these two histogram charts, the x axis reports symptoms, other than the last column, medications. These are subjective complaints, not objective findings. Each active group consists of only 12 subjects, yet the reporting stratifies the data into four different levels of complaints and uses percent rather than raw numbers.

Converting percent back to raw numbers and using a binary reporting for "Yes" symptom is present and "No" symptom is not present, we can covert percentage to raw numbers. Placebo effects were minor and not addressed here.

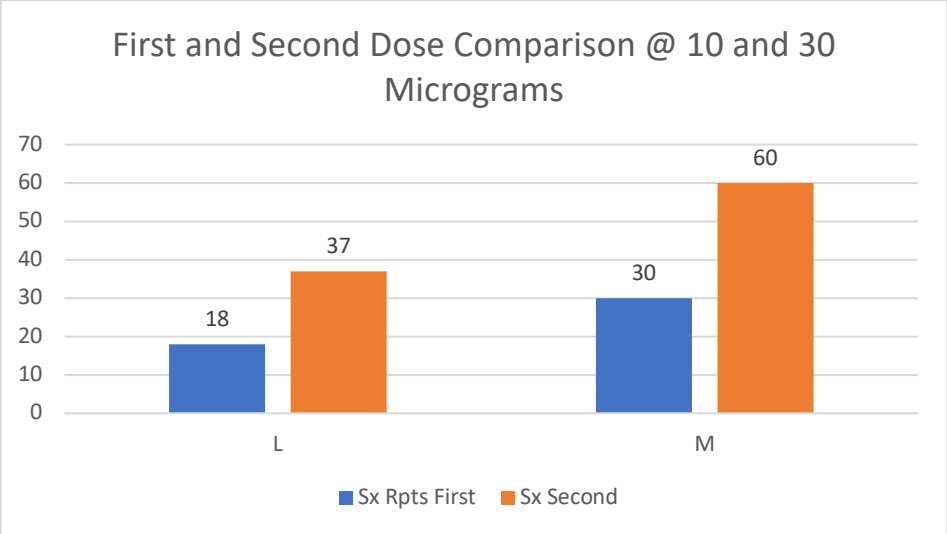
First Dose	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Jt. Pain	Meds	Total
10	1	4	5	1	2	1	2	2	18
30	1	6	6	7	1	1	2	6	30
100	6	10	9	10	4	7	3	10	59



The first dose shows increased symptom reporting associated with increasing dose of mRNA. (L = 10 µg, M = 30 µg and H = 100 µg.) The 100 µg dose was dropped for dose 2.

Comparing 1st and 2nd doses:

30 µg	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Joint Pain	Meds	Total
1st	1	6	6	7	1	3	0	6	30
2nd	9	10	12	8	1	7	3	10	60
Incr.	8	4	6	1	-1	6	1	4	29
% incr.	800%	67%	100%	14%	-50%	600%	50%	67%	48%



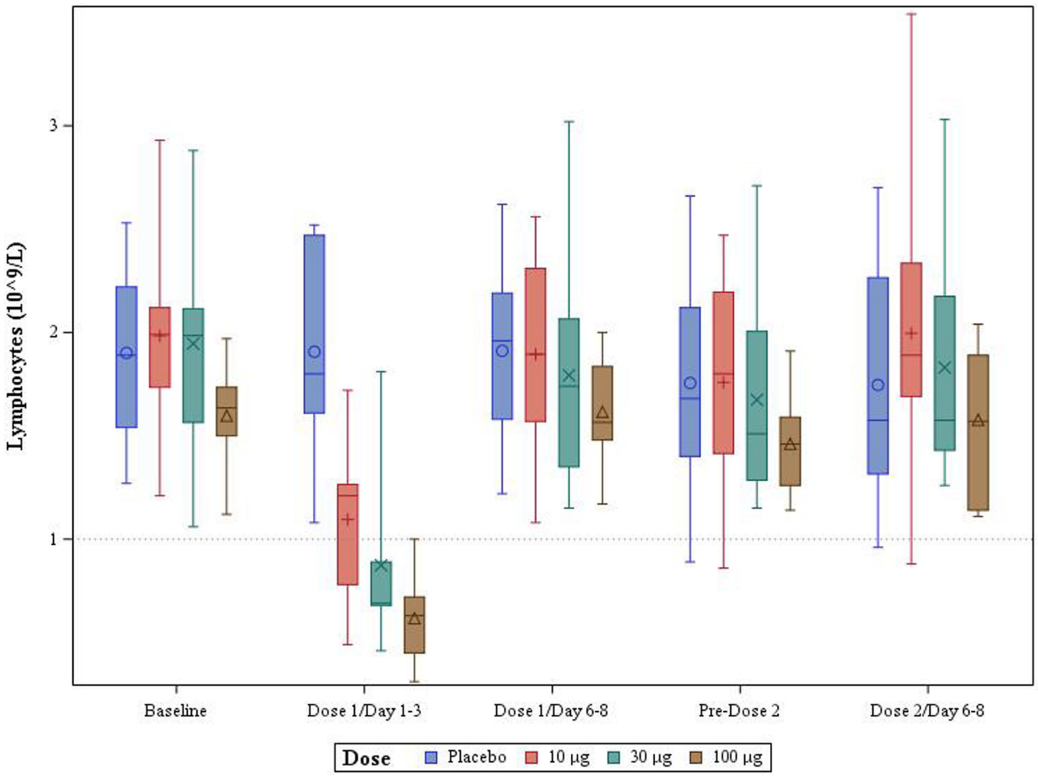
Conclusion: Increased symptoms occur with increased µg dose of BNT162b1. Increased symptoms were reported after the second dose at 10 µg and 30 µg compared with the first dose. The differences in the number of adverse events between different dosages of the "vaccine" other than Placebo versus 10 µg are statistically significant, $p < 0.05$. **(See Appendix).**

Trial #	1	2	1	2	1
Dose	10	10	30	30	100
Pain	7	10	12	12	12
Redness	0	0	2	2	4
Swelling	0	0	0	2	5

Pain, redness and swelling was reported but was not very useful other than a dose effect may be present for pain at the site of injection. Redness can be very subjective, and swelling is very difficult to determine.

Objective findings including blood pressure, heart rate, fever, temperature, respiratory rate, physical examinations and complete laboratory findings were not reported and are not available on the Pfizer web site.

Extended Data Figure 1: Lymphocyte changes following three dosing levels as a function of time



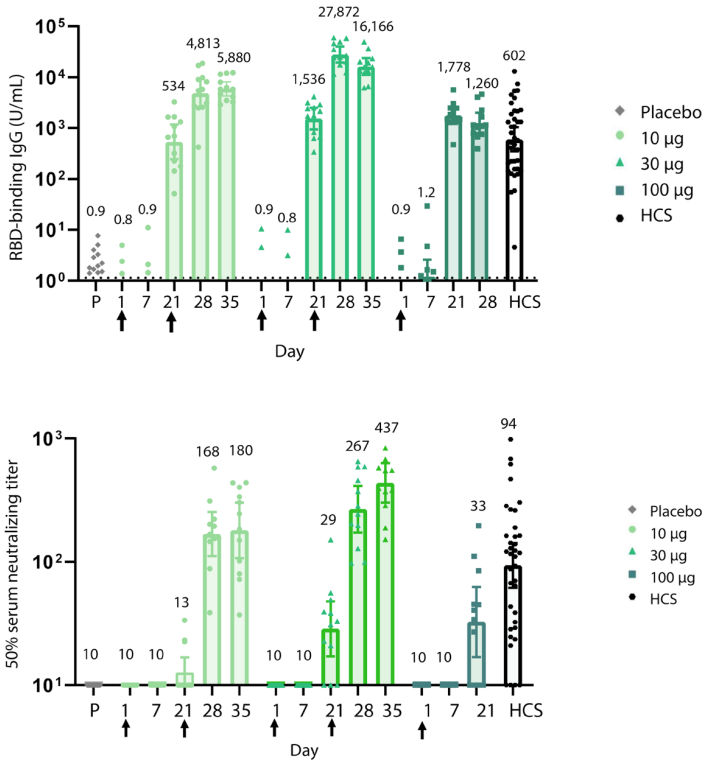
Lymphocytopenia on Days 1-3 after the first dose occurred in 1/12, 5/11, 6/12 for 10 µg, 30 µg and 100 µg respectively. **No lymphocyte reporting is given following the second dose during the comparable interval, Day 1-3, which after the first dose produced substantial drops in lymphocytes.** 1/12 (10 µg), 1/11 (30 µg) and 4/12 (100 µg) had Grade 3 decreases in lymphocytes. Neutropenia occurred in two subjects, one each in the 10 µg and 30 µg groups. No explanation for the decrease in lymphocytes and neutrophils is given. The reporting of raw data is required here, not a verbal description.

There is a lymphocyte measurement for a second dose @100 µg whereas the text "Based on the reactogenicity reported after the first dose of 100 µg and the second dose of 30 µg participants who received an initial 100 µg dose **did not receive a second 100 µg dose**." P2 p4

The schematic in Figure 1 also indicates no second 100 µg doses were given. Yet, there is a plot of second dose of 100 µg as indicated by the brown data candle plot on the far right. Was a second 100 µg dose given or not?

Finally, the variance in lymphocyte counts in the second dose 30 µg group appears to be very high. Was there a lymphocytosis as well as lymphocytopenia? Why? We need the actual data here. What caused the lymphocytopenia and were these cases associated with lymphadenopathy and or splenomegaly?

Immune Response:



Immune response was assessed using geometric mean titers of RBD-binding IgG concentrations at baseline, 7 and 21 days after dose 1 and at 7 and 14 days after dose two in the 10 and 30 µg groups. The 100 µg dose was given only once according to this chart. A second assessment using neutralizing titers showed increases after the second dose.

Discussion:

"Our study had several limitations. **While we used convalescent sera as a comparator, the kind of immunity (T cells versus B cells or both) and level of immunity needed to protect from COVID-19 are unknown.**"

"Further, this analysis of available **data did not assess immune responses or safety beyond 2 weeks after the second dose of vaccine. Both are important to inform the public health use of this vaccine.**"

"Follow -up will continue for all participants and will include collection of SAEs for 6 months and COVID-19 infection and multiple additional immunogenicity measurements through up to two years."

"The clinical testing of BNT162b1 described here has taken place in the context of a broader, ongoing COVID-19 vaccine development program. That **program includes the clinical testing of three additional vaccine candidates** including candidates encoding the full-length spike, and a parallel trial in Germany, in which additional immune responses including neutralizing responses against variant strain and cell-mediated responses are being assessed (US manuscript in preparation).[24]"

"The clinical findings for the BNT162b1 RNA-based vaccine candidate are encouraging and strongly support accelerated vaccine candidate development, including efficacy testing, and at-risk manufacturing to maximize the opportunity for the rapid production of a SARS-CoV-2 **vaccine to prevent COVID-19**."

Comments/Questions:

BNT162b1 not BNT162b2 was used in this Phase I/II clinical trial. What are the differences between the two? Was there a Phase I/II trial for BNT162b2? Why was the substitution made?

Was the 100 µg dose repeated or not? Extended Data Figure 1 shows a data plot for the 100 µg dose at Dose 2 Day 6-8.

The researchers erroneously believed that the mRNA in BNT162b1 would be transient, briefly producing spike protein then being metabolized and gone with no translation into host DNA. There is now concern that BNT162b2 mRNA code may be incorporated into the host genome based on a study by Alden, et al. (See page 1 for the citation). Similar concerns were raised by Zhang, et al. with regard to SC2 viral mRNA.

Clinical findings reported in this paper are deficient in presenting adequate detailed findings and should have body weight changes, appetite, and symptom changes during the reporting intervals, vital signs, physical findings and complete laboratory results.

This study was published in August 2020. Where are the reports noted as pending in the paper?

What role did N1-methyl-Pseudouridine (1MP) have in the unexpectedly long bioavailability of mRNA products? If not, what is the mRNA longevity attributable to? Does this enhanced stability have anything to do with dropping the lymphocyte counts noted in the Pre-Clinical studies?

The 100-µg dose not only suppressed lymphocytes but had a marked decline in immune response compared with immune sera and lower doses of BNT162b1. How and why did this happen? Is BNT162b1/BNT162b2 toxic to lymphocytes?

The objective of the vaccine was to prevent COVID-19. This product failed to prevent COVID-19. This product failed to prevent illness, hospitalization and death from COVID-19.

Was a risk benefit analysis performed? If so, where can the document be found?

Appendix: Statistical Analysis

How to interpret results:

The first two tests are the Chi Square test. The leftmost numbers are:
1 10 mg Yes (number of adverse events)
2 10 mg No (number of without adverse events)
3 30 mg Yes
4 30 mg No
5 100 mg Yes
6 100 mg no

A simple data transformation was required to use the Chi Square test. All numbers were multiplied by 10.

The first number under each AE category is the number of events (X10)
The second number under each AE category is the expected number of events
The third number is the Chi Square statistic.

The larger the Chi Square statistic, the more unusual the event.

The p values of both dose 1 and dose 2 Chi Square test are less than 0.05 and therefore the test is statistically significant.

The six other tests are Test of Proportions. It is the total number of all categories of AE divided by the total number of events.

All but the first (10 mg vs. placebo), are statically significant.

Chi-Square Test: Fever, Fatigue, Headache, Chills, Diarrhea, Muscle Pain, Joint

1st Dose without placebo X 10

Expected counts are printed below observed counts.
Chi-Square contributions are printed below expected counts.

	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Joint Pain
1	10	40	50	10	20	10	20
	22.50	22.50	22.50	22.50	22.50	22.50	22.50
	6.944	13.611	33.611	6.944	0.278	6.944	0.278
2	110	80	70	110	100	110	100
	97.50	97.50	97.50	97.50	97.50	97.50	97.50
	1.603	3.141	7.756	1.603	0.064	1.603	0.064
3	10	60	60	70	10	30	0
	37.50	37.50	37.50	37.50	37.50	37.50	37.50
	20.167	13.500	13.500	28.167	20.167	1.500	37.500
4	110	60	60	50	110	90	120
	82.50	82.50	82.50	82.50	82.50	82.50	82.50
	9.167	6.136	6.136	12.803	9.167	0.682	17.045
5	60	100	90	100	40	70	30
	73.75	73.75	73.75	73.75	73.75	73.75	73.75
	2.564	9.343	3.581	9.343	15.445	0.191	25.953
6	60	20	30	20	80	50	90
	46.25	46.25	46.25	46.25	46.25	46.25	46.25
	4.088	14.899	5.709	14.899	24.628	0.304	41.385
Total	360	360	360	360	360	360	360

	Medication	Total
1	20	180
	22.50	
	0.278	
2	100	780
	97.50	

0.064

3 60 300
37.50
13.500

4 60 660
82.50
6.136

5 100 590
73.75
9.343

6 20 370
46.25
14.899

Total 360 2880

Chi-Sq = 496.633, DF = 35, P-Value = 0.000

Results for: 2nd Dose wo placebo x 10

Chi-Square Test: Fever, Fatigue, Headache, Chills, Diarrhea, Muscle Pain, Joint

Expected counts are printed below observed counts.
Chi-Square contributions are printed below expected counts.

	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Joint Pain
1	10	80	100	30	0	50	40
	46.25	46.25	46.25	46.25	46.25	46.25	46.25
	28.412	24.628	62.466	5.709	46.250	0.304	0.845
2	110	40	20	90	120	70	80
	73.75	73.75	73.75	73.75	73.75	73.75	73.75
	17.818	15.445	39.174	3.581	29.004	0.191	0.530
3	90	100	120	80	10	70	30
	75.00	75.00	75.00	75.00	75.00	75.00	75.00
	3.000	8.333	27.000	0.333	56.333	0.333	27.000
4	30	20	0	40	110	50	90
	45.00	45.00	45.00	45.00	45.00	45.00	45.00
	5.000	13.889	45.000	0.556	93.889	0.556	45.000
Total	240	240	240	240	240	240	240

	Medication	Total
1	60	370
	46.25	

4.088

2 60 590
73.75
2.564

3 100 600
75.00
8.333

4 20 360
45.00
13.889

Total 240 1920

Chi-Sq = 629.452, DF = 21, P-Value = 0.000

Test and CI for Two Proportions 10 µg vs p

Sample X N Sample p
1 18 96 0.187500
2 7 72 0.097222

Difference = p (1) - p (2)
Estimate for difference: 0.0902778
95% CI for difference: (-0.0135438, 0.194099)
Test for difference = 0 (vs not = 0): Z = 1.70 P-Value = 0.088

Test and CI for Two Proportions 30 µg vs p

Sample X N Sample p
1 30 96 0.312500
2 7 72 0.097222

Difference = p (1) - p (2)
Estimate for difference: 0.215278
95% CI for difference: (0.100039, 0.330516)
Test for difference = 0 (vs not = 0): Z = 3.66 P-Value = 0.000

Test and CI for Two Proportions 100 µg vs p

Sample X N Sample p
1 59 96 0.614583
2 7 72 0.097222

Difference = p (1) - p (2)
Estimate for difference: 0.517361
95% CI for difference: (0.398360, 0.636362)
Test for difference = 0 (vs not = 0): Z = 8.52 P-Value = 0.000

Test and CI for Two Proportions 30 µg vs 10 µg

Sample	X	N	Sample p
1	30	96	0.312500
2	18	96	0.187500

Difference = p (1) - p (2)
Estimate for difference: 0.125
95% CI for difference: (0.00378499, 0.246215)
Test for difference = 0 (vs not = 0): Z = 2.02 P-Value = 0.043

Test and CI for Two Proportions 100 µg vs 10 µg

Sample	X	N	Sample p
1	59	96	0.614583
2	18	96	0.187500

Difference = p (1) - p (2)
Estimate for difference: 0.427083
95% CI for difference: (0.302286, 0.551881)
Test for difference = 0 (vs not = 0): Z = 6.71 P-Value = 0.000

Test and CI for Two Proportions 100 µg vs 30 µg

Sample	X	N	Sample p
1	59	96	0.614583
2	30	96	0.312500

Difference = p (1) - p (2)
Estimate for difference: 0.302083
95% CI for difference: (0.167638, 0.436528)
Test for difference = 0 (vs not = 0): Z = 4.40 P-Value = 0.000

Dose 1:

Dosage - Reaction	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Joint Pain	Meds	Total
10 µg Yes	1	4	5	1	2	1	2	2	18
10 µg No	11	8	7	11	10	11	10	10	78
30 µg Yes	1	6	6	7	1	3	0	6	30
30 µg No	11	6	6	5	11	9	12	6	66
100 µg Yes	6	10	9	10	4	7	3	10	59
100 µg No	6	2	3	2	8	5	9	2	37
p Yes	0	2	3	0	0	0	0	2	7
p No	9	7	6	9	9	9	9	7	65
Total	45	45	45	45	45	45	45	45	360

Dose 2:

Dosage - Reaction	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Joint Pain	Meds	Total
10 µg Yes	1	8	10	3	0	5	4	6	37
10 µg No	11	4	2	9	12	7	8	6	59
30 µg Yes	9	10	12	8	1	7	3	10	60
30 µg No	3	2	0	4	11	5	9	2	36
p Yes	0	2	0	0	0	0	0	0	2
p No	6	4	6	6	6	6	6	6	46
Total	30	30	30	30	30	30	30	30	240

Report 4: "Review of 'Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine' by Fernando P. Polack, MD, et al." – Team 5

Team Five: Review of Polack with comments and questions.

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

Fernando P. Polack, M.D., Stephen J. Thomas, M.D., Nicholas Kitchin, M.D., Judith Absalon, M.D., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Gonzalo Perez Marc, M.D., Edson D. Moreira, M.D., Cristiano Zerbini, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., Satrajit Roychoudhury, Ph.D., Kenneth Koury, Ph.D., Ping Li, Ph.D., Warren V. Kalina, Ph.D., David Cooper, Ph.D., Robert W. Frenck, Jr., M.D., Laura L. Hammitt, M.D., Ozlem Türeci, M.D., Haylene Nell, M.D., Axel Schaefer, M.D., Serhat Unal, M.D., Dina B. Tresnan, D.V.M., Ph.D., Susan Mather, M.D., Philip R. Dormitzer, M.D., Ph.D., Uğur Şahin, M.D., Kathrin U. Jansen, Ph.D., and William C. Gruber, M.D., for the C4591001 Clinical Trial Group*

NEJM 383:27 12/31/2020.

Abstract:

BNT162b2: full length spike protein, nucleoside modified

21,720 BNT162b2 21728 Placebo

Severe covid after first dose:

- 9 in Placebo group
- 1 in BNT162b2

Cases of covid onset after at least 7 days after second dose:

- 8 cases in BNT162b2
- 162 cases in Placebo:

"The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of adverse events was low and was similar in the vaccine and placebo groups." P2603, p3.

Main Body of Paper:

"A two-dose regimen of BNT162b2 conferred 95% protection against Covid-19 in persons 16 years or older. Safety over a median of 2 months was similar to that of other viral vaccines. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728)", P2603 p4.

"Safe and effective prophylactic vaccines are urgently needed to contain the pandemic, which has had devastating medical, economic, and social consequences." P2604 p 1.

"Findings from studies conducted in the United States and Germany among healthy men and women showed that two 30 mg doses of BNT162b2 elicited high SARS-CoV-2 neutralizing antibody titers and robust antigen-specific CD8+ and Th1-type CD4+ cell responses."

"Here we report safety and efficacy findings from the phase 2/3 part of a global phase 1/2/3 trial evaluating the safety, immunogenicity, and efficacy of 30 mg of BNT162b2 in preventing Covid-19 in persons 16 years of age or older." P2604 p3.

"Collection of phase data on vaccine immunogenicity of phase 2/3 data on vaccine immunogenicity and the durability of the immune response to immunization is ongoing, and those data are not reported here." P 2604 p 3.

Study group included HIV, hep B or C patients.

Exclusion: Prior history of covid-19, immunosuppression. P. 2604 p 5.

Pfizer conducted trials, collected the data, performed the data analysis, data interpretation, and the writing of the manuscript. "This data set and these trial results are the basis for an application for emergency use authorization.[9]" P2604 p 3.

Study Design:

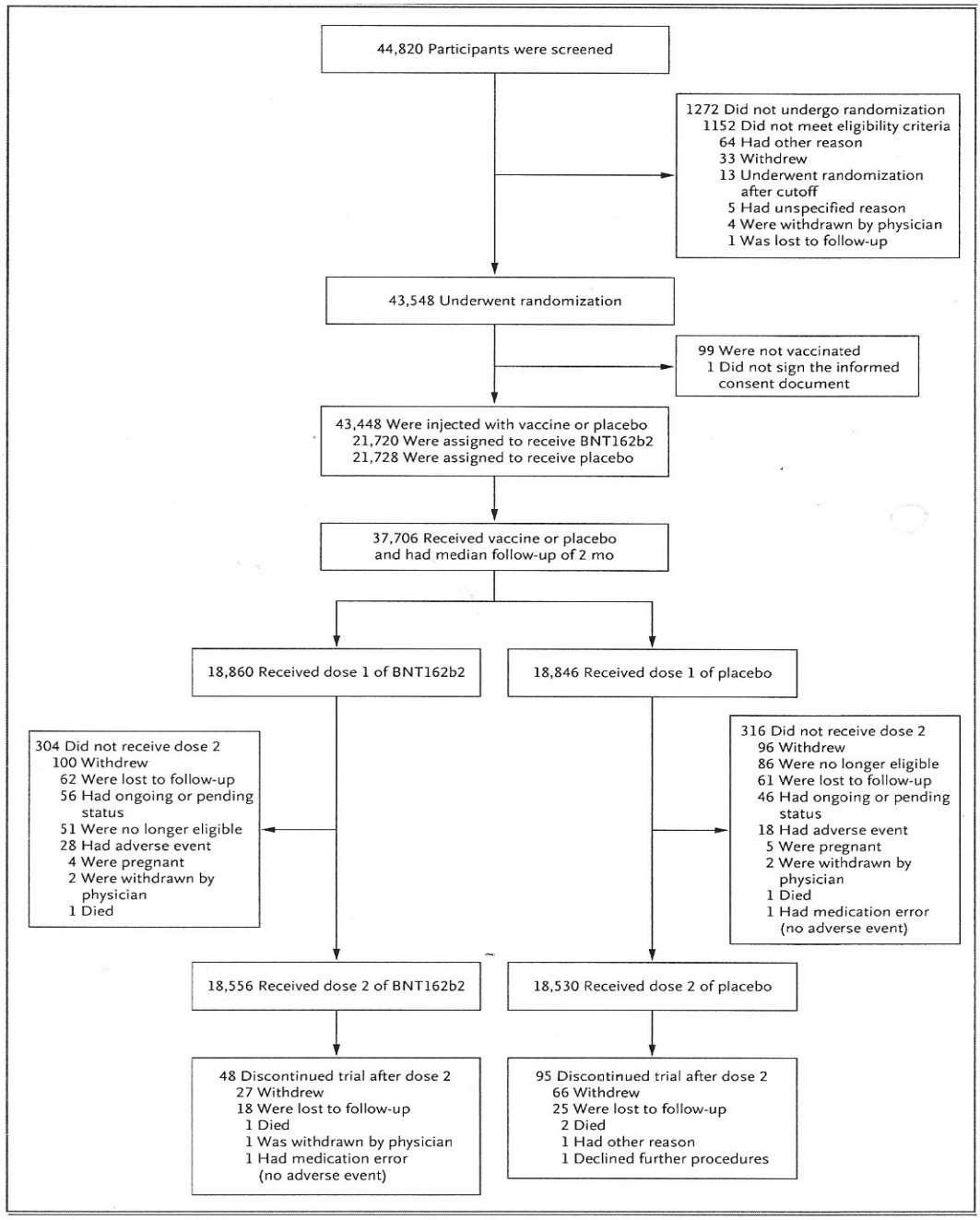


Table S1, Online Supplementary Appendix: Explanation of the various denominator values for use in assessing the results (available https://www.nejm.org/)

Figure/Table Number	Figure/Table Title	Population(s)/Sample Size	Explanation
Figure 1	Disposition of participants (CONSORT)	All enrolled population N=37,706 "main safety subset"	All randomized ≥16 years of age, N=43,548 • [minus 99 non-vaccinated, 1 no ICD] Vaccinated N=43,448 Main safety subset (N=37,706) needed to have been enrolled by October 9, 2020 for EUA application
Figure 2	Local and Systemic Reactions Reported within 7 Days after Receipt of 30 µg BNT162b2 or Placebo by Age Group	Reactogenicity subset of ≥16 years old N=8,183	Per protocol
Figure 3	Efficacy of BNT162b2 against COVID-19 Occurrence after Dose 1	N=43,355 (modified intention-to-treat)	All randomized >=12 years of age N= 43,651 • [minus 99 non-vaccinated, 1 no ICD] Vaccinated (dose 1 efficacy) N=43,551 • [minus 196 HIV+] All efficacy N=43,355
Table 1	Demographics	N=37,706 main safety subset	As above
Table 2	Vaccine Efficacy against COVID-19 from 7 Days after Dose 2 [Primary Endpoints]	1st primary efficacy endpoint: Includes those **without** evidence of prior infection (N=36,523) 2nd primary efficacy endpoint: Includes those **with and without** evidence of prior infection (N=40,137)	Evaluable population: • received 2 vaccinations as randomized • no major protocol deviations Excludes HIV+
Table 3	Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection Prior to 7 Days After Dose 2	N=36,523 (same as 1st primary endpoint)	
Table S2	Baseline Comorbidities	N=37,706 main safety subset	
Table S3	Participants Reporting at Least 1 Adverse Event From Dose 1 (All Enrolled Participants)	N=43,252	Vaccinated N=43,448 minus 196 HIV+
Table S4	Vaccine Efficacy from 7 Days After Dose 2 by Underlying Comorbidities among Participants without Evidence of Infection Prior to 7 Days after Dose 2	N=36,523 (same as 1st primary endpoint)	
Table S5	Vaccine Efficacy of Severe COVID-19 Occurrence after Dose 1 (Modified Intention-to-Treat)	N=43,355 (modified intention-to-treat)	See comments to Figure 3

Table S1 | Explanation of the Changes in Denominator Numbers in Various Analyses.

7

- 44,820 subjects screened & 43,448 participants injected:
  - BNT162b2
    - 18,860 dose 1: 28 withdrew after adverse reaction.
    - 18,556 dose 1 & 2: 48 discontinued after second
    - 18,508 dose 1 & 2: completed two-month follow-up

        - Placebo

            - 18,846 dose 1: 18 withdrew after adverse reaction.
            - 18,530 dose 1 & dose 2: 95 discontinued after 2nd
            - 18,435 dose 1 & dose 2 completed 2-month follow-up.

    - 43,355 subjects Modified intention-to-treat (mITT) efficacy population.

        - All age groups 12 years of age or older.
        - 100 participants who were 12 to 15 years of age "...contributed to person time years but included no cases." P2605 p5.

    - 40,137 subjects evaluated 7 days after the second dose "with or without evidence of prior infection".

    - 37,706 subjects "Safety population" (defined by the FDA):

        - Persons 16 years of age or older.
        - Median of 2 months of follow-up as of October 9, 2020.

    - 36,523 subjects evaluated for efficacy 7 days after the second dose and "who had no evidence of prior infection".

    - 8183 subjects = Reactogenicity Subset

Methods:

"Participants received two injections, 21 days apart, of either BNT162b2 or placebo, delivered in the deltoid muscle." P2604 p6. Aspiration not mentioned.

Adults 16 years of age or older who were:

- Healthy or had
- Stable chronic medical conditions, including but not limited to
    - Human immunodeficiency virus (HIV),
    - Hepatitis B virus, or
    - Hepatitis C virus infection

Division of work:

- Pfizer:

    1. Design and conduct of the trial,
    2. Data collection,
    3. Data analysis and interpretation
    4. Writing of the manuscript.

- BioNTech:

    - Trial sponsor
    - Manufactured BNT162b2
    - Contributed: interpretation of the data and the writing of the manuscript.

- **All the trial data were available to <u>all the authors</u>, who <u>vouch for its accuracy and completeness and for adherence of the trial to the protocol</u>, which is available with the full text of this article at NEJM.org. This data was not on the web site 4/13/2022.**

- An independent data and safety monitoring board reviewed efficacy and unblinded safety data.

Safety:

- Observation for 30 minutes after injection.

- Solicited data:

    1. End points.
    2. Specific local or systemic adverse events.
    3. Use of antipyretic or pain medication within 7 days after the receipt of each dose of vaccine or placebo, as prompted by and recorded in an electronic diary in a subset of participants (the reactogenicity subset)

- Unsolicited: Unsolicited serious adverse events through 6 months after the second dose.

- Adverse event data through approximately 14 weeks after the second dose are included.

- Safety data are reported for all participants who provided informed consent and received at least one dose of vaccine or placebo.

- Per protocol, safety results for participants infected with HIV (196 patients) will be analyzed separately and are not included here.

- A stopping rule for the theoretical concern of vaccine-enhanced disease was to be triggered if the one-sided probability of observing the same or a more unfavorable adverse severe case split (a split with a greater proportion of severe cases in vaccine recipients) was 5% or less, given the same true incidence for vaccine and placebo recipients. Alert criteria were to be triggered if this probability was less than 11%.

Efficacy:

Efficacy of BNT162b2 against **confirmed Covid-19**:

- First Primary Endpoint: Onset of confirmed Covid-19 at least 7 days after the second dose in participants who had been without serologic or virologic evidence of SARS-CoV-2 infection up to 7 days after the second dose. P. 2604

  Restated: Confirmed Covid-19 after 28 days following the initial dose. Covid-19 positives prior to 28 days were considered unvaccinated. P2605 p 3.

  - Confirmed Covid Diagnosis: FDA criteria. (No reference provided).

    - **One** of the following Symptoms:
      - Fever
      - Chills
      - Diarrhea
      - Vomiting
      - Loss of Taste
      - Loss of smell
      - New or increased:
        - Cough
        - SOB
        - Muscle pain

    - Plus: a respiratory specimen in suspected SC2 + by NAAT obtained during symptomatic period +/- four days before.

- Second Primary Endpoint: was "efficacy in participants with and without evidence of prior infection." P2605 p 3.

- Major secondary endpoints: Efficacy against severe covid. "Details are provided in the protocol." P2605 p4.

  - Confirmed covid.

  - One of the following:
    - Respiratory failure.
    - Acute neurologic event.
    - Renal dysfunction.
    - Hepatic dysfunction.
    - ICU Admission.
    - Death.

Results:

Reactogenicity: n = 8183.

Local:

- Younger recipients reported symptoms more often than older >55

Local Pain	< 55	>= 55
First Dose	83%	71%
Second Dose	78%	66%

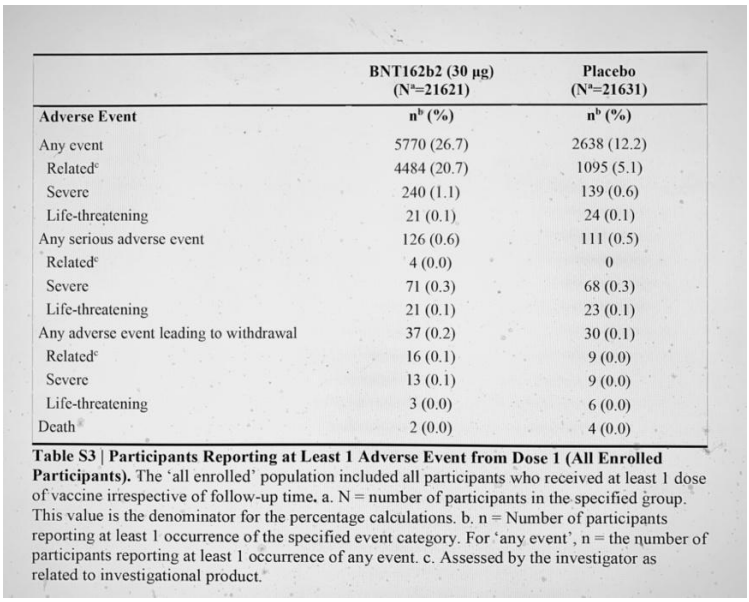
.

- **Systemic:** More reports after second dose than first:

  - Fatigue: 59% <55, 51% => 55, placebo 23%
  - Headache: 51% < 55, 39% = >55, placebo 24%
  - Temperature > 38 Deg C after second dose:
    - 16% < 55, 11% => 55
    - 38.9-40 deg C: 0.2% after 1st dose, 0.8% after 2nd dose; 0.1% placebo 1st and 2nd.
    - > 40 deg C: 2 subjects one in injected and placebo.

- Antipyretic/analgesic:
    - < 55: dose 1 = 28% & dose 2 = 45%.
    - => 55: dose 1 = 20% & dose 2 = 38%.
    - Placebo: dose 1 = 10 % & dose 2 = 14%.

Adverse Events: Table S3 (available online):



	BNT162b2 (30 µg) (N[a]=21621)	Placebo (N[a]=21631)
Adverse Event	**n[b] (%)**	**n[b] (%)**
Any event	5770 (26.7)	2638 (12.2)
Related[c]	4484 (20.7)	1095 (5.1)
Severe	240 (1.1)	139 (0.6)
Life-threatening	21 (0.1)	24 (0.1)
Any serious adverse event	126 (0.6)	111 (0.5)
Related[c]	4 (0.0)	0
Severe	71 (0.3)	68 (0.3)
Life-threatening	21 (0.1)	23 (0.1)
Any adverse event leading to withdrawal	37 (0.2)	30 (0.1)
Related[c]	16 (0.1)	9 (0.0)
Severe	13 (0.1)	9 (0.0)
Life-threatening	3 (0.0)	6 (0.0)
Death	2 (0.0)	4 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 (All Enrolled Participants). The 'all enrolled' population included all participants who received at least 1 dose of vaccine irrespective of follow-up time. a. N = number of participants in the specified group. This value is the denominator for the percentage calculations. b. n = Number of participants reporting at least 1 occurrence of the specified event category. For 'any event', n = the number of participants reporting at least 1 occurrence of any event. c. Assessed by the investigator as related to investigational product.

n= 43,252 according to the published article. P2608 p 3.
n = 43,252 according to online Table S1 P 7. "Vaccinated N=43,448 minus 196 HIV+."
n = 43,252 according to online Table S3 P 9. "All enrolled." At least 1 dose.
Any Event, Any Event Related and Any Event Severe are statistically significant, Appendix 1.

	BNT162b2	Placebo
n =	21621	21631
All events	5770	2638
Related	4484	1095
% AE React	69%	31%
% All AE Total	27%	12%
% Rel. AE Total	21%	5%

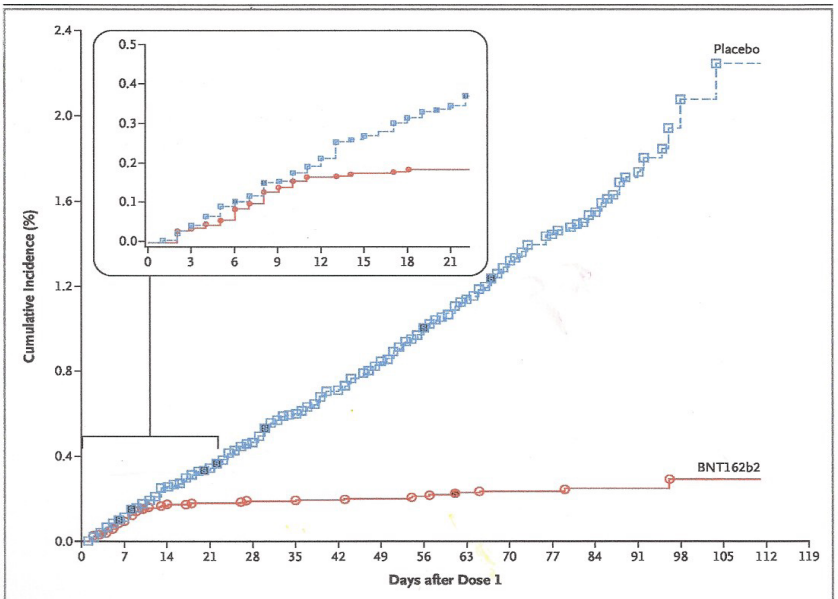
Rel = Related AE; P = Placebo

	BNT162b2	Placebo
Lymphadenopathy	64	6

Efficacy:

	BNT162b2	**Placebo**	**VE***
n =	18198	18325	
Surveillance Time	2.214	2.222	
Covid-19: >= 28 days after dose 2	**8**	80	
Covid-19: <28 days after dose 2+ Placebo	39	82	52%
All	47	162	
Study comparison	8	162	95%

*VE = Vaccine Efficacy



Efficacy End-Point Subgroup	BNT162b2, 30 μg (N=21,669)		Placebo (N=21,686)		VE (95% CI)
	No. of participants	Surveillance time *person-yr (no. at risk)*	No. of participants	Surveillance time *person-yr (no. at risk)*	*percent*
Covid-19 occurrence					
After dose 1	50	4.015 (21,314)	275	3.982 (21,258)	82.0 (75.6–86.9)
After dose 1 to before dose 2	39		82		52.4 (29.5–68.4)
Dose 2 to 7 days after dose 2	2		21		90.5 (61.0–98.9)
≥7 Days after dose 2	9		172		94.8 (89.8–97.6)

Figure 3. Efficacy of BNT162b2 against Covid-19 after the First Dose.
Shown is the cumulative incidence of Covid-19 after the first dose (modified intention-to-treat population). Each symbol represents Covid-19 cases starting on a given day; filled symbols represent severe Covid-19 cases. Some symbols represent more than one case, owing to overlapping dates. The inset shows the same data on an enlarged y axis, through 21 days. Surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from the first dose to the end of the surveillance period. The confidence interval (CI) for vaccine efficacy (VE) is derived according to the Clopper–Pearson method.

Discussion:

"A two-dose regimen of BNT162b2 (30 μg per dose, given 21 days apart) was found to be safe and 95% effective against Covid-19."

"The vaccine met both primary efficacy endpoints, with more than a 99.99% probability of a true vaccine efficacy greater than 30%."

"These results met our prespecified success criteria, which were to establish a probability above 98.6% of true vaccine efficacy being greater than 30%, and greatly exceeded the minimum FDA criteria for authorization.9"

"...in the interval between the first and second doses, the observed vaccine efficacy against Covid-19 was 52%, and in the first 7 days after dose 2, it was 91%, reaching full efficacy against disease with onset at least 7 days after dose 2."

"Of the 10 cases of severe Covid-19 that were observed after the first dose, only 1 occurred in the vaccine group. This finding is consistent with overall high efficacy against all Covid-19 cases."

"The severe case split provides preliminary evidence of vaccine mediated protection against severe disease, alleviating many of the theoretical concerns over vaccine-mediated disease enhancement.11"

"Although the study was designed to follow participants for safety and efficacy for 2 years after the second dose, given the high vaccine efficacy, ethical and practical barriers prevent following placebo recipients for 2 years without offering active immunization, once the vaccine is approved by regulators and recommended by public health authorities."

Comments/Questions:

1. Diagnosis of covid-19 required only one symptom and a positive NAAT test. Why was only one symptom + a positive NAAT rather than an actual clinical diagnosis based upon symptoms, signs, and supportive laboratory data?

2. NAAT have proven unreliable leaving only one symptom as the basis to diagnose covid-19. Are there any other studies of experimental gene therapy that are dependent upon a single symptom to diagnose a disease? How can this be adequate?

3. What NAAT was used and what are the statistics for false negatives and positives? Was the same test used throughout the study?

4. Aspiration was not reported as the technique for injection of the BNT162b2.

5. "All the trial data", reported to have been available to all the authors, is no longer available with the full text of the article at NEJM.org as reported in the text. Why not?

6. Participants received "informed consent". Where can the consent documenting risks, benefits and alternatives be found?

7. Were participants with prior infection with SC2 included or not?

8. Where is the raw data for reactogenicity?

9. Complete reporting of symptoms, signs, laboratory and diagnostic studies is not provided.

10. Table S2 lists 14 disease categories after consolidating All Malignancies, Diabetes, and Liver Disease. The CDC identifies 21 disease categories.[1]

    a. There were 18 subjects with dementia. What legal process was required for each of these individuals? How were they able to communicate their symptoms?

    b. What was the distribution of comorbidities the control versus experimental groups given that a major risk factor is clustering of comorbidities in subjects? Data presented in Table S2 provides no information about clustering of comorbidities in the study subjects. Some studies have indicated that covid-19 fatalities were associated with multiple comorbidities average 3.8 per fatality.

    c. Hypertension is a major risk factor that was not reported.

    d. Coronary artery disease and arrhythmia are risk factors for covid-19 and Prevalence Data was not reported.

    e. The number of smokers and drug users was not given.

    f. Age is a continuous variable. It is also a risk factor. Table 1 gives age data for 16-55 and >55 years. These categories are overly broad. More granular data is required.

11. "The incidence of serious adverse events was similar in the vaccine and placebo groups (0.6% and 0.5%, respectively)." This data needs to be carefully examined. P2610 p2.

12. "Lymphadenopathy, which generally resolved within 10 days, is likely to have resulted from a robust vaccine-elicited immune response." Given that lymphocytopenia is associated with BNT162b2, are there other explanations for lymphadenopathy? Was splenomegaly found in these cases? What were the lymphocyte counts for study subjects?

13. "...the occurrence of adverse events more than 2 to 3.5 months after the second dose and more comprehensive information on the duration of protection remain (sic) to be determined." Shouldn't a longer follow-up period be required given the experimental nature of this gene therapy?

14. Physicians look to the NEJM as a trusted source for guiding their recommendations to patients. This publication is quite superficial given the gravity of the pandemic and the implications of administering this drug to a significant portion of the human race.

15. The medical files of all covid-19 patients should be carefully reviewed as well as random sampling of the study population.

Appendix 1:

Test and CI for Two Proportions Any Event Sample 1 Vax Sample 2 Placebo

Sample	X	N	Sample p
1	5770	21621	0.266870
2	2638	21631	0.121955

Difference = p (1) - p (2)
Estimate for difference: 0.144916
95% CI for difference: (0.137582, 0.152249)
Test for difference = 0 (vs not = 0): Z = 38.73 P-Value = 0.000

Test and CI for Two Proportions Related Events Sample 1 Vax Sample 2 Placebo

Sample	X	N	Sample p
1	4484	21621	0.207391
2	1095	21631	0.050622

Difference = p (1) - p (2)
Estimate for difference: 0.156769
95% CI for difference: (0.150626, 0.162913)
Test for difference = 0 (vs not = 0): Z = 50.02 P-Value = 0.000

Test and CI for Two Proportions Severe Events Sample 1 Vax Sample 2 Placebo

Sample	X	N	Sample p
1	240	21621	0.011100
2	139	21631	0.006426

Difference = p (1) - p (2)
Estimate for difference: 0.00467436
95% CI for difference: (0.00291817, 0.00643054)
Test for difference = 0 (vs not = 0): Z = 5.22 P-Value = 0.000

Test and CI for Two Proportions Any Serious AE Sample 1 Vax Sample 2 Placebo

Sample	X	N	Sample p
1	126	21621	0.005828
2	111	21631	0.005132

Difference = p (1) - p (2)
Estimate for difference: 0.000696143
95% CI for difference: (-0.000695265, 0.00208755)

Appendix 2:

	Pfizer Co-Morbidities		CDC Co-Morbidities
1	AIDS/HIV	1	Cancer
2	Any Malignancy	2	Chronic Kidney Disease
3	Cerebrovascular Disease	3	Chronic Liver Disease
4	Chronic Pulmonary Disease	4	Chronic Lung Disease
5	Congestive Heart Failure	5	Cystic Fibrosis
6	Dementia Report	6	Dementia
7	Diabetes With Chronic Complication	7	Diabetes
	Diabetes Without Chronic Complication	8	Disabilities
8	Hemiplegia or Paraplegia	9	Heart Conditions
	Leukemia	10	HIV/AIDS
	Lymphoma	11	Immunocompromised
	Metastatic Solid Tumor	12	Mental Health
9	Mild Liver Disease	13	Obesity
	Moderate or Severe Liver Disease	14	Inactivity
10	Myocardial Infarction	14	Pregnancy
11	Peptic Ulcer Disease	16	Sickle Cell Disease
12	Peripheral Vascular Disease	17	Smoking
13	Renal Disease	18	Solid organ/Stem Cell Transplant
14	Rheumatic Disease	19	Stroke or CVA
		20	Substance Use
		21	Tuberculosis

Report 5: "Pfizer mRNA Construct: Why Spike Protein Causes Disease" by Daniel Demers, PhD – Team 5.

Daily Clout 4/20/22 Report: Pfizer mRNA Construct
Researcher/Author: Daniel B. Demers, PhD
Reviewed by: Team 5
Team 5 Leader: Linnea Wahl

Introduction

In the first paragraph of Pfizer document 2.4 NONCLINICAL OVERVIEW, Pfizer states that "BNT162b2 is a nucleoside modified mRNA (modRNA) expressing full-length S [spike] with two proline mutations (P2) to lock the transmembrane protein in an antigenically optimal prefusion conformation" (p. 6, https://phmpt.org/wp-content/uploads2022/03/125742_S1_M2_24_nonclinical-overview.pdf).

They list two references (Pallesen et al., 2017; Wrapp et al., 2020) as their justification for this design. That is the end of Pfizer's discussion on why that particular design was selected, and it appears that Pfizer conducted no further research before selecting this design (or construct) and proceeding with vaccine development. This, as it turns out, is quite important.

Concerns Regarding the Pfizer mRNA Construct

There are three primary concerns regarding the Pfizer approach used to design their mRNA vaccine.

1. The basic Pfizer construct utilizing two proline substitutions to stabilize the spike protein molecule is flawed, and the protein molecule as well as the mRNA itself, remain unstable.

2. The spike protein has been shown to cause disease; therefore, a vaccine based on the spike protein will promote pathogenesis, not prevent it.

3. The S1 subunit of the spike protein has been shown to shed into the circulatory system, thereby furthering disease.

The following discussion expands on these three concerns.

Concern 1: Pfizer selected the Pallesen et al. (2017) construct as the basis for the Pfizer vaccine.

The work described by Pallesen et al. (2017) was performed on the MERS-CoV virus. Pallesen selected proline substitutions based on the work of others (Qiao et al., 1998; Sanders et al., 2002; Krarup, et al., 2015).

Pfizer also references a paper in the journal *Science* authored by Daniel Wrapp (Wrapp et al., 2020). Wrapp cites Pallesen et al. (2017) and the work of Robert Kirchdoerfer et al. (2018) who evaluated the Pallesen-style double proline substitutions (S2P) in the spike protein of SARS-CoV. Wrapp et al. (March 2020) assessed the 2P substitution in the spike protein of SARS-CoV-2, evaluating the construct for its affinity for the host cell receptor ACE2. Wrapp did not evaluate the SARS-CoV-2 S2P antigenicity nor the fate of the S1 subunit that is shed when the spike protein binds to the cell.

Wrapp et al. (March 2020) states that "Knowing the atomic level structure of the SARS-CoV-2 spike will allow for additional protein engineering efforts that ***could*** [emphasis added] improve antigenicity and protein expression for vaccine development." It appears that Pfizer took this article and used it as is to create a vaccine without "additional protein engineering efforts" as suggested by Wrapp et al. (2020).

Moreover, the purpose of introducing two proline substitutions into the spike protein as described by Pallesen and Wrapp (Pallesen et al., 2017; Wrapp et al., 2020; Pfizer, p. 6, https://phmpt.org/wp-content/uploads2022/03/125742_S1_M2_24_nonclinical-overview.pdf) was to stabilize the spike protein to improve its thermal **stability, conformation and antigenicity**. But, as stated by Hsieh et al. (2020)

with co-author Daniel Wrapp, “even with these (2P) substitutions the SARS-CoV-2 S-protein remains unstable and difficult to produce reliably in mammalian cells, hampering R&D of subunit vaccines.”

Hsieh and Wrapp (Hsieh et al., July 2020) found that 26 of 100 variants that they created and tested had higher expression than the S-2P substitution that Pfizer selected. One of their variants, labeled Hexa-Pro, contained four proline substitutions in addition to the S-2P substitutions and had nearly 10X greater expression, had improved thermal stability and retained the desired conformation.

Numerous articles since then state that the 2P substitution used by Pallesen/Pfizer is unstable (McCallum et al., 2020, posted on-line Aug. 2020; Xiong et al., 2020; Brun et al., 2020; Juraszek et al., 2021). *Brun et al. (posted November 2020) even made suggestions for improving the Pfizer BNT162b2 vaccine after describing why it was a suboptimal design*.

Why did Pfizer select the Pallesen construct requiring storage in ultra-low-temperature freezers when the HexaPro construct is more stable, can be stored at room temperature and has much greater expression?

Concern 2: Pfizer did not address the well-documented pathogenesis caused by the coronavirus spike protein before release of their vaccine and before FDA approval.

In a 2005 article, Kuba demonstrated that SARS-CoV spike protein injected into mice worsened their lung disease (Kuba, 2005).

In 2008, Wang et al. demonstrated that the receptor binding domain (RBD) of the spike protein of SARS-CoV leads to internalization of ACE2, resulting in downregulation and subsequent lung injury (Wang et al., 2008). *The authors concluded that “because the RBD spike binding to ACE2 contributes to SARS pathogenesis, the use of subunit vaccines based on RBD spike should be considered carefully.”*

Wang et al. (2020) and Semimukai et al. (2020) noted that recombinant spike protein induced antibodies in mice and protected against SARS-CoV infection, but lung eosinophilic immunopathology was observed in the immunized mice after SARS infection.

Elizabeth M. Rhea and her co-authors reported on-line in December 2020 and published in March 2021 (Rhea et al., 2021) that S1 subunit labeled with radioiodine (I-S1) readily crosses the mouse blood-brain-barrier (BBB) and could explain the adverse effects of S1 and/or SARS-CoV-2 such as encephalitis, respiratory difficulties and reduced ability to smell. I-S1 was also detected in kidney, liver and spleen.

In January 2021, Letarov et al. published an article in the journal *Biochemistry (Moscow),* titled *Free Sars-CoV-2 Spike Protein S1 Particles May Play a Role in the Pathogenesis of COVID-19 Infection* (Letarov et al., 2021). They noted that the upregulation of cell surface expression of ACE1 and/or downregulation of ACE2 can lead to pulmonary damage. This occurs during SARS infection and by recombinant SARS-CoV spike protein. They hypothesize that S1 molecules carry intact RBDs, and their binding to ACE2 may induce ACE2 downregulation and deleterious downstream effects such as increased inflammation, thrombosis, and pulmonary damage.

Letarov et al. (2021) also reference the work of Zhang et al. (2020) who elucidated a spike protein mutation in SARS-CoV-2 (the D614G variant) that is associated with increased infectivity but reduced S1 shedding and mild symptoms. This is further evidence that the spike protein is responsible for pathogenesis.

Nuovo et al. (2021, posted on-line Dec. 2020) reported on the endothelial cell damage caused by the S1 subunit of the spike protein. They reported two main findings: 1) Human COVID-19 cases demonstrated microvessel endothelial damage in the brain and other organs, including the skin, due to circulating spike protein that induces cytokine production resulting in microencephalopathy; and 2) injection of the S1 full-length spike subunit into mice (but not the S2 subunit) induced an equivalent microvascular encephalopathy as seen in

human COVID-19 cases. The authors further note that although their study *"focused on the brain, it should be stressed that there are other sites where there is a rich bed of microvessels with the ACE2 receptor, including skin/subcutaneous fat and the liver. As has been documented in human patients, microvessels at these sites can also display an endothelialitis that, in the skin/fat can induce complement activation/hypercoagulable state and the so called cytokine storm typical of fatal COVID-19."*

"In sum, the data presented indicates that the full length S1 subunit of the spike protein of SARS-CoV-2 alone is capable, without the infectious virus, of inducing systemic microendothelial cell damage in mice with a cognate pattern of complement activation and increased cytokine expression and the concomitant thrombosis/hypercoagulable state. This disease pattern strongly parallels the extra-pulmonary manifestation of severe human COVID-19 and suggests that the latter may not represent systemic infectious virus. Thus, prevention of the CNS disease so common in severe COVID-19 may require neutralization/removal of the circulating pseudovirus."

Lei et al. (April 2021) created a pseudovirus exhibiting spike protein but containing no virus inside and concluded that the spike protein alone is sufficient to cause damage to the vascular endothelial cells.

With so much evidence demonstrating a direct link between the presence of the spike protein S1 subunit in the circulatory system and pathogenesis, why would Pfizer create a vaccine that not only injects spike protein into the patient, but converts the cells of the patient into "spike protein factories" that turn out the spike protein S1 subunit, the very molecule that causes illness?

Concern 3: Pfizer did not address the well-documented shedding of the coronavirus spike protein into the circulatory system, where it crosses over to multiple organ systems to cause pathogenesis, before release of their vaccine.

It was shown as early as 1994 (Bullough et al., 1994) that the surface spike protein of an enveloped virus (Influenza) would release a subunit after proteolytic cleavage of the structure upon binding to the host cell surface. Work by Alexandra Walls (2017) demonstrated that the proteolytic processing of coronavirus spike proteins allows shedding of the S1 subunit.

Brun et al. (posted on-line November 2020) reported the process by which spike protein is processed within the host cell and soluble S1 subunit was secreted into the extracellular space via lysosomes. Their work indicated that the production of spike vaccine antigen protein without a virus to incorporate the protein into the viral envelope created an overexpression system and secretion of the protein by the cell (shedding). They suggest that the secreted spike proteins do not mimic the spike glycoproteins as they are presented on the actual virus and may effectively act as a decoy, eliciting more of the unwanted sub-optimal, non-neutralizing antibodies that are incapable of neutralizing the virus.

The authors state that the Pfizer BNT162b vaccines (and other similar type vaccines) rely on the supplied RNA sequence to use the host cell machinery to faithfully produce the spike protein in its fully folded, glycosylated and assembled state, resembling a natural infection, and they trigger a robust innate and humoral response; however, this does not happen. They go on to suggest a better vaccine design, one that abolishes the furin cleavage site (which is intact in the Pfizer construct) and introduces mutations that lock the spike protein in the prefusion conformation to prevent shedding and elicit a more potent antibody response.

Rhea et al. (2021, posted on-line December 2020) noted that coronavirus spike proteins are often cleaved; therefore, S1 could be shed and shed S1 may cross the BBB. Shedding of the S1 subunit of the spike protein was also noted by Liu et al. (2020), Letarov et al. (2021), Rhea et al. (2020), Zhang et al. (2020) and Henderson et al. (2020).

Given that the Pfizer mRNA construct design is sub-optimal; given that it has been well established (since 2005 to 2008) that spike proteins cause disease; and given that the spike protein S1 subunit is shed during binding of the virus or pseudovirus with the host cell, as well as secreted by host cells producing spike protein following injection with an mRNA-derived spike protein vaccine, why would Pfizer develop and release an mRNA vaccine that demonstrates all three of these deleterious qualities? Why would Pfizer develop and release an mRNA vaccine that demonstrates poor design with limited immunogenicity, requires storage at very low temperatures, and results in the production of a spike protein that readily sheds into the circulatory system to cause pathogenesis in multiple organ systems? And why would the FDA approve it?

References:

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Bullough, P., et al., Nature, 1994; 371:37-43. Structure of Influenza haemagglutinin at the pH of membrane fusion.

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Juraszek, J., et al., Nature Communications, 2021; 12, Article number 244. Stabilizing the closed SARS-CoV-2 spike trimer.

Kirchdoerfer, R., et al., Scientific Reports, 2018; 8:15701; DOI:10.1038/s41598-018-34171-7. Stabilized coronavirus spikes are resistant to conformational changes induced by receptor recognition or proteolysis.

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Lei, Y., et al., Circulation Research. 2021; 128:1323-1326. SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2.

Letarov, A., et al., Biochemistry (Moscow), 2021; 86(3):257-261. Free SARS-CoV-2 Spike Protein S1 Particles May Play a Role in the Pathogenesis of COVID-19 Infection.

Liu, C., et al., Structure, 2020; 28(11):1218-1224. The Architecture of Inactivated SARS-CoV-2 with Postfusion Spikes Revealed by Cryo-EM and Cryo-ET.

McCallum, M., et al., Nature Structural & Molecular Biology, October 2020; 27:942–949. Structure-guided covalent stabilization of coronavirus spike glycoprotein trimers in the closed conformation.

Nuovo, G., et al. Annals of Diagnostic Pathology 51, 2021; 151682. Endothelial cell damage is the central part of COVID-19 and a mouse model induced by injection of the S1 subunit of the spike protein.

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Semimukai et al., Microbiol Immunol, 2020; 64:33-51. Gold nanoparticle-adjuvanted S protein induces a strong antigen-specific IgG response against severe acute respiratory syndrome-related coronavirus infection, but fails to induce protective antibodies and limit eosinophilic infiltration in lungs.

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Wang, Y., et al., J Med Virol, 2020; 93:892-898. SARS-CoV-2 S1 is superior to the RBD as a COVID-19 subunit vaccine antigen.

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Xiong, X., et al., Nat Struct Mol Biol, October 1, 2020; 27(10):934-941. A thermostable, closed SARS-CoV-2 spike protein trimer.

Zhang, L., et al., bioRxiv. Preprint. June 12, 2020. The D614G mutation in the SARS-CoV-2 spike protein reduces S1 shedding and increases infectivity.

Report 6: "Safe and Effective? We Beg to Differ. Red Flags in the Pfizer Internal Documents." – Team 3.

Pfizer released the documents on their early efficacy and safety trials of their vaccine. (Pfizer 2.7.3 SUMMARY OF CLINICAL EFFICACY). https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf.

The results of these documents are used to justify the claim the vaccines are safe and effective. Examine the document! It is evident beyond any doubt. Pfizer lied and misled; and upon this foundational lie, Moderna, and public health authorities, built the lie so big that it is believed alongside continual repetition that the mRNA vaccines are 'safe and effective.'

Herein we will examine these claims, deconstruct them, and prove them false, using well-established foundational science.

Why did Pfizer want the original documents sealed for 75 years, buried in the labyrinth of the governmental archives, hidden in plain sight? After 75 years, the documents may be forgotten; or if not forgotten lost, and if found by some future scholar, stripped of their legal implication. Released after everyone who received the vaccine is dead. Released after those responsible for bringing this plague upon the world are dead. So, we ask: If there is nothing to hide, why hide it? And this is so curious as they are already immune from legal action under the mantle of the EUA (with the profound power of the Federal Government protecting them). But the EUA immunity has an Achilles heel: If the EUA was granted on fraud, the Government is immune from legal action, but Pfizer is not.

This brings us to the essential question: Is the vaccine safe and efficacious? An in-depth look at Pfizer's own documents challenges these assertions. The evidence is in plain sight. The vaccines are not proven safe nor effective. We need to know that they knew, and when they knew it. But as medical professionals, there is a higher burden. If they did not know, but they should have known because the knowledge was published in peer review literature, have they committed medical malfeasance?

First, we must look at the difference between vaccine efficacy and vaccine effectiveness. There is similarity. Vaccine efficacy and vaccine effectiveness measure the proportionate reduction in cases among vaccinated persons. Vaccine efficacy is used when a study is carried out under ideal conditions, for example, during a clinical trial. Vaccine effectiveness is used when a study is carried out under typical field (that is, less than perfectly controlled) conditions (Principles of Epidemiology | Lesson 3 - Section 6 (cdc.gov), https://www.cdc.gov/csels/dsepd/ss1978/lesson3/section6.html). A vaccine may show efficacy in a clinical trial but be utterly ineffective when introduced at a societal level. This non-effectiveness may be due to unanticipated safety concerns (aka, excessive adverse

reactions reported) or more subtle immunological reasons due to immune imprinting (aka, doctrine of original antigenic sin)(Monto, A. S., Malosh, R. E., Petrie, J. G., & Martin, E. T. (2017). The Doctrine of Original Antigenic Sin: Separating Good from Evil. *J Infect D* https://doi.org/10.1093/infdis/jix173). In all cases, a vaccine can only be declared effective after widespread deployment at a societal level, and a risk/reward benefit has been determined. For a vaccine against a disease such as COVID-19, where the risk from the disease is only to a segment of the population, and the overall risk to society is extremely low, there needs to be essentially no risk or adverse reactions from the vaccine. Pfizer's need to hire 2,400 personnel to deal with the unexpected adverse reactions of the vaccines, essentially precludes the designation of the vaccine as "effective".

We have historical precedent to help us understand this. The CDC uses two primary systems to monitor the safety of vaccines. Vaccine Adverse Event Reporting System (VAERS) and Vaccine Safety Datalink (VSD). VAERS is an early warning system that helps CDC and FDA monitor problems following vaccination. VSD is a collaboration between CDC and eight integrated health care organizations. (Vaccine Safety Datalink VSD | Monitoring | Ensuring Safety | Vaccine Safety | CDC). In 1967, the usual seasonal flu was replaced by a more virulent strain known as H1N1 swine flu. A vaccine was brought to market to combat this variant. The result was an unacceptably high level of Guillain-Barre (a neurological dysfunction of ascending motor paralysis). The vaccine was withdrawn as non-effective. (Guillain-Barré syndrome and Flu Vaccine | CDC).(Breman, J. G., & Hayner, N. S. (1984). Guillain-Barré syndrome and its relationship to swine influenza vaccination in Michigan, 1976-1977. *Am J Epidemiol*, *119*(6), 880-889. https://doi.org/10.1093/oxfordjournals.aje.a113810)

The interesting thing about COVID-19 is that we are told that the VAERS system is unreliable (Gorski, D. (2022, January 7). *As 2021 shambles to a close, the misuse of VAERS by anti vaxxers continues apace*. Science-Based Medicine. https://sciencebasedmedicine.org/as-2021-shambles-to-a-close-the-misuse-of-vaers-by-antivaxxers-continues-apace/). And yet, it is sponsored by the CDC and despite a multi-billion-dollar budget, never upgraded to fix its deficiencies. How does the CDC see the VAERS database? Healthcare providers are required by law to submit any adverse events following vaccination. (CDC) COVID -19 vaccination requires its own reporting. (CDC). VAERS system is seen as underreporting not overreporting adverse events. (CDC). So, which is it? Government incompetence, government malfeasance of the highest official public health figure in the land, or the current VAERS system is highly valuable? The only valid conclusion is that the CDC sees the current VAERS system as incredibly valuable.

Is the Pfizer vaccine (as well as Moderna and other vaccines) safe? There is a basic problem. Each vaccine has its own proprietary formula. The conflation of all the vaccines into the single heading "the vaccines are safe" is not warranted and care must be taken to designate which vaccine is under discussion.

There is a very high standard to declare a vaccine safe. This standard is higher for a vaccine than for a medication. (Santa Clara University, & Burrell, A. (2021, March 11). *First, do harm: The ethics of human challenge trials for COVID-19 vaccine development*. Markkula Center for Applied Ethics. Retrieved April 29, 2022, from https://www.scu.edu/ethics/healthcare-ethics-blog/first-do-harm-the-ethics-of-human-challenge-trials-for-covid-19-vaccine-development/) This is derived from the first principle of medicine "First, do no harm." The physician assesses the patient, renders a diagnosis, and then prescribes medication. In the decision to prescribe a medication, the physician must balance the good of the medication against the harm of the medication against the disease of the individual. Several situations demonstrate the issue. A patient is suffering from cancer. The use of a chemotherapeutic agent may save the patient's life but also may have serious and life-threatening side effects. A common dilemma for a physician is the patient suffering from a cold who demands an antibiotic. The physician knows the cold is due to a virus and will not respond to the antibiotic and so will not prescribe it for the cold. But he/she may reason that a cold often leads to a bacterial infection and an antibiotic will prevent that and so prescribes the antibiotic. If a healthy patient comes to a physician requesting medication, but in which the physician cannot find reasonable grounds to prescribe the medication, the physician is obligated not to give that patient medication as it violates the first principle. The reason is obvious. Every medication has a potential negative side effect. If the patient is healthy, and any medication is given, there is the potential to do harm.

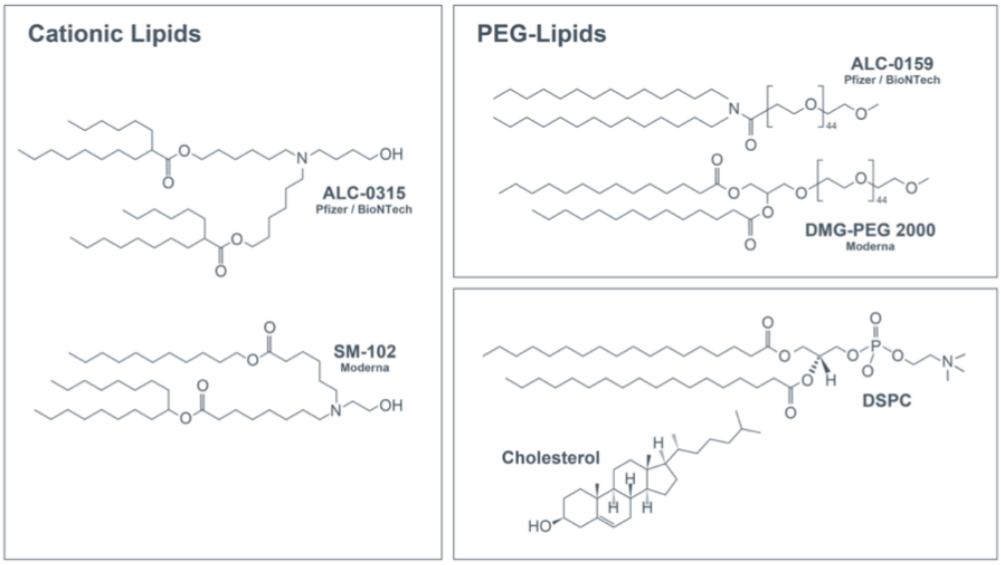
In the case of a vaccine the situation is fundamentally different. The patient is healthy and there is a desire to prevent disease. But the vaccine itself may have undesirable side effects. Any harm to the patient is now weighed against the good to society. If the vaccination is for a terrible plague such as smallpox or polio the answer is clear: Everyone is at risk. The diseases are devastating to everyone, and the side effects are minimal. Not giving the vaccine is harmful and so the first principle is violated. As such, the vaccination is offered to healthy people.

In the case of COVID-19, this standard is not reached. The disease is only harmful to a small segment of the population and that harm must be weighed against the potential harm of a vaccine to a much larger segment of the population not at risk. The question now presents itself: is there sufficient evidence that the COVID-19 vaccine is essentially harmless to the general population? The answer presents itself as it is summed up in the idiom, "the facts speak for themselves". The demand of vaccine manufacturers against legal liability of their vaccines indicate that the manufacturers do not consider the vaccines safe. The need for Pfizer to hire 2400 full-time employees to evaluate adverse effects from the vaccine speaks for itself. The action by public medical officials to impeach the VAERS reporting system speaks for itself. The only valid conclusion: The Pfizer vaccine is not safe.

There are two paths that both lead to the conclusion that the Pfizer vaccine is not safe and effective. The first is the construction of the vaccine and the second is the construction of the study to evaluate the vaccine.

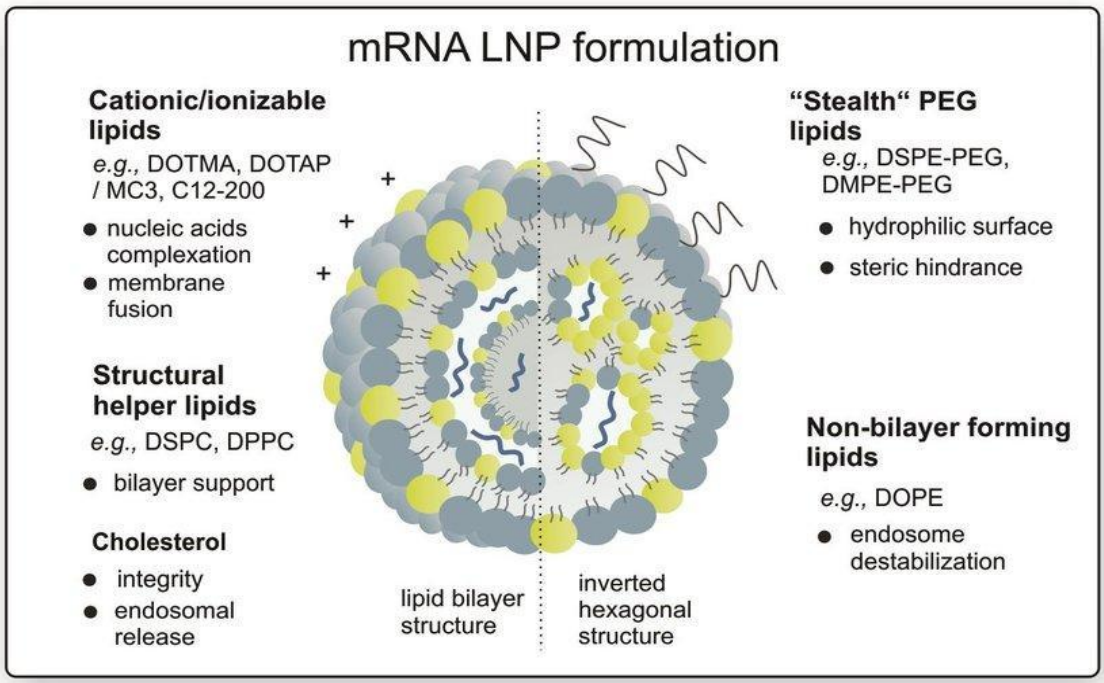
To start, let's look at the vaccine. It is a marvel of biotechnology. It consists of four separate components. (Pardi, N., Hogan, M. J., Porter, F. W., & Weissman, D. (2018). mRNA vaccines - a new era in vaccinology. *Nat Rev Drug Discov*, *17*(4), 261-279. https://doi.org/10.1038/nrd.2017.243). A mRNA core, surrounded by a lipid nanoparticle (ALC 0315 for Pfizer or SM-102 for Moderna; see diagram). This lipid nanoparticle is positively charged and will attach itself to the mRNA. It is surrounded by negatively charged PEG coating, and an emulsifier. The mRNA directs the cell to make the spike protein of the virus. The lipid nanoparticle, PEG and emulsifier helps get the mRNA into the cell. (Schlich, M., Palomba, R., Costabile, G., Mizrahy, S., Pannuzzo, M., Peer, D., & Decuzzi, P. (2021). Cytosolic delivery of nucleic acids: The case of ionizable lipid nanoparticles. *Bioeng Transl Med*, *6*(2), e10213. https://doi.org/10.1002/btm2.10213),(Lipid Nanoparticle - Creative Biolabs (creative-biolabs.com), (Kowalski, P. S., Rudra, A., Miao, L., & Anderson, D. G. (2019). Delivering the Messenger: Advances in Technologies for Therapeutic mRNA Delivery. *Mol Ther*, *27*(4), 710-728. https://doi.org/10.1016/j.ymthe.2019.02.012) Each component has its own use and its own potential hazard. Each component must be assessed for safety. And then the entire combination must be assessed for safety.

Figure 1 : Covid -19 nanotechnology in vaccines



https://www.cas.org/ja/resource/blog/understanding-nanotechnology-covid-19-vaccines

Figure 2: mRNA LNP formulation Verbeke et al., 2019



Verbeke, R., Lentacker, I., de Smedt, S. C., & Dewitte, H. (2019). Three decades of messenger RNA vaccine development. *Nano Today*, *28*, 100766. https://doi.org/10.1016/j.nantod.2019.10076

The basic dictum of toxicology, the study of body toxins, is that all things are potentially toxins, and it is the dose that makes the difference.(Grandjean, P. (2016). Paracelsus Revisited: The Dose Concept in a Complex World. *Basic Clin Pharmacol Toxicol*, *119*(2), 126-132. https://doi.org/10.1111/bcpt.12622), (Frank, P., & Ottoboni, M. A. (2011). *The dose makes the poison* (3rd ed.). Wiley.) From this, two things follow: The mRNA directs the cell to make the spike protein of the virus (without making the entire viral particle). It is essential to demonstrate that the spike protein is innocuous. It is essential to demonstrate that the lipid nanoparticle delivery system is harmless.

Evaluation of the lipid nanoparticle delivery system:

The lipid nanoparticle delivery system used for vaccines was initially designed to deliver medicines and for gene therapy. It is the mechanism used to deliver chemotherapy for brain tumors and is designed to penetrate the blood brain barrier. The blood brain barrier (BBB) protects the brain from environmental hazards, including medicines and pathogens, such as bacterial and viruses. This barrier is overcome by lipid nanoparticles.(Shankar, R., Joshi, M., & Pathak, K. (2018). Lipid Nanoparticles: A Novel Approach for Brain Targeting. *Pharm Nanotechnol*, *6*(2), 81-93. https://doi.org/10.2174/2211738506666180611100416)

This is our first area of concern. Lipid based nano therapy is acceptable for chemotherapy to target highly malignant brain tumors because the inherent disease is so deadly to the patient that any negative side effect of the delivery system, except the immediate death of the patient, can be ignored. In this setting, they are considered less toxic than alternatives, but this does not mean they are not toxic to the brain. (Shankar, 2018, et al). The situation for a vaccine is fundamentally different. The recipient is healthy. Any evaluation of the safety of this delivery system for a vaccine needs to evaluate whether penetration of the blood brain barrier by the lipid nanoparticle delivery system conveys its own harm. Studies have proven that ENMs (engineered nanomaterials) that can cross or bypass the blood–brain barrier and then access the central nervous system, carry the potential of neurotoxicity (Ge D, Du Q, Ran B, et al. The neurotoxicity induced by engineered nanomaterials. *Int J Nanomedicine*. 2019;14:4167-4186. Published 2019 June 6. doi:10.2147/IJN.S203352). This evaluation was never done in the Pfizer safety and efficacy trials. **Therefore, it is impossible to know whether the vaccine is safe in this arena. Pfizer did not prove the safety of the nano-lipid delivery system for the brain.**

A second question is whether the COVID-19 virus can hitch a ride on the delivery vehicle to penetrate the brain during the period when someone may be infected, full of replicating virus, but asymptomatic. It is known that a carrier is likely to be infectious during the asymptomatic replication phase of the virus. It is also known that the virus is capable of directly infecting cells. This question remains unanswered as such an evaluation is never done by Pfizer.

We were told ad nauseam that the injection would stay at the injection site. However, it was known since the inception of lipid nanoparticle delivery systems that they enter the systemic circulation and can find their way to many end points.(Christensen, J., Litherland, K., Faller, T., van de Kerkhof, E., Natt, F., Hunziker, J., . . . Swart, P. (2014). Biodistribution and metabolism studies of lipid nanoparticle-formulated internally [3H]-labeled siRNA in mice. *Drug Metab Dispos*, *42*(3), 431-440)

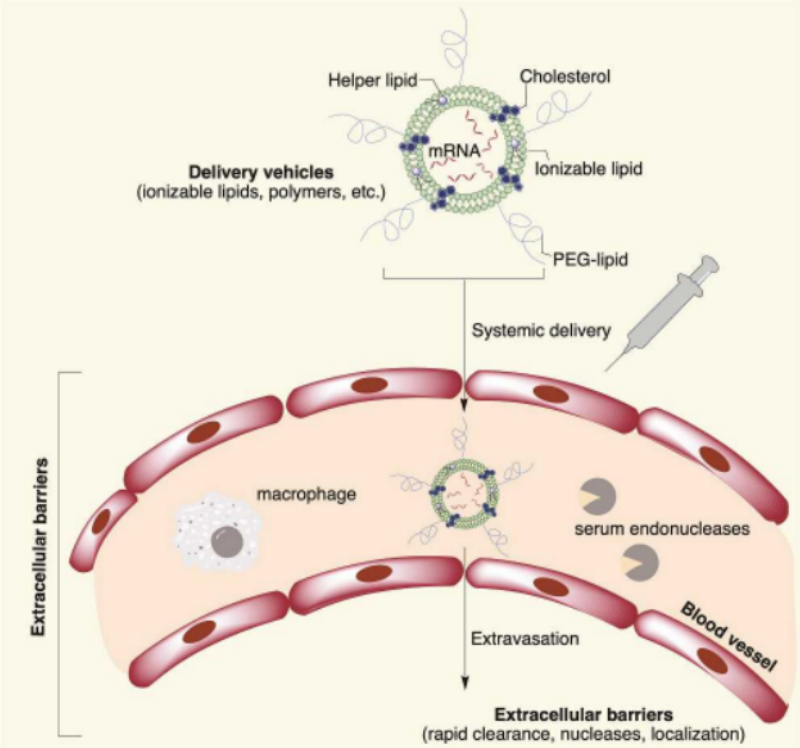


Fig.3 Schematic representation of extra- and intracellular barriers for mRNA delivery. (Kowalski, 2019)

This property of the mRNA/lipid nanoparticle delivery is utilized in many medications, and in fact, forms the basis of utilizing such delivery systems for chemotherapy for brain tumors, melanomas, and potentially other cancers(Lainé, A. L., Gravier, J., Henry, M., Sancey, L., Béjaud, J., Pancani, E., . . . Passirani, C. (2014). Conventional versus stealth lipid nanoparticles: formulation and in vivo fate prediction through FRET monitoring. *J Control Release*, *188*, 1-8. https://doi.org/10.1016/j.jconrel.2014.05.042) (Kowalski, P. S., Rudra, A., Miao, L., & Anderson, D. G. (2019). Delivering the Messenger: Advances in Technologies for Therapeutic mRNA Delivery. *Mol Ther*, *27*(4), 710-728. https://doi.org/10.1016/j.ymthe.2019.02.012) It is known almost from inception that the size of the lipo-nanoparticle and the exact chemical composition determine the distribution throughout the body and various tissues.(Lainé et al., 2014),(Hirsjärvi, S., Dufort, S., Gravier, J., Texier, I., Yan, Q., Bibette, J., . . . Coll, J. L. (2013). Influence of size, surface coating and fine chemical composition on the in vitro reactivity and in vivo biodistribution of lipid nanocapsules versus lipid nanoemulsions in cancer models. *Nanomedicine*, *9*(3), 375-387. https://doi.org/10.1016/j.nano.2012.08.005). **Therefore, it was known that the vaccine injection would not stay at the injection site. Stating that the vaccine would stay at the injection site is a lie of commission. As this information was not evaluated, it could not be concluded that the vaccine was safe.**

The mRNA lipid nanoparticle is wrapped with PEG (also known as ALC 0159). PEG is utilized in many medications, as well as foodstuffs and cosmetics. The incidence of severe allergic reaction to PEG (known as anaphylaxis, a life-threatening event) is rising as PEG is becoming more common in the environment. (Troelnikov, A., Perkins, G., Yuson, C., Ahamdie, A., Balouch, S., Hurtado, P. R., & Hissaria, P. (2021). Basophil reactivity to BNT162b2 is mediated by PEGylated lipid nanoparticles in patients with PEG allergy. *J Allergy Clin Immunol*, *148*(1), 91-95. https://doi.org/10.1016/j.jaci.2021.04.032),(Erdeljic Turk, V. (2021). Anaphylaxis associated with the mRNA COVID-19 vaccines: Approach to allergy investigation. *Clin Immunol*, *227*, 108748. https://doi.org/10.1016/j.clim.2021.108748) (Sellaturay, P., Nasser, S., Islam, S., Gurugama, P., & Ewan, P. W. (2021). Polyethylene glycol (PEG) is a cause of anaphylaxis to the Pfizer/BioNTech mRNA COVID-19 vaccine. In *Clin Exp Allergy* (Vol. 51, pp. 861-863). https://doi.org/10.1111/cea.13874),(Kim, M. A., Lee, Y. W., Kim, S. R., Kim, J. H., Min, T. K., Park, H. S., . . . Chang, Y. S. (2021). COVID-19 Vaccine-associated Anaphylaxis and Allergic Reactions: Consensus Statements of the KAAACI Urticaria/Angioedema/Anaphylaxis Working Group. *Allergy Asthma Immunol Res*, *13*(4), 526-544. https://doi.org/10.4168/aair.2021.13.4.526). Although the consent form for the vaccine mentions the possibility of severe allergic reaction and anaphylaxis, it does not overtly tell the recipient that this is in the vaccine. If a person knows they have a PEG allergy, such a warning would warn them against receiving the vaccine. Likewise, the emulsifiers used in the vaccine delivery system may also induce an anaphylactic-like reaction. **The vaccine is clearly not safe for someone who has an allergy to PEG and or related emulsifiers. The warning should be more overt.**

The heart of the vaccine is modified mRNA. (Kim, S. C., Sekhon, S. S., Shin, W. R., Ahn, G., Cho, B. K., Ahn, J. Y., & Kim, Y. H. (2022). Modifications of mRNA vaccine structural elements for improving mRNA stability and translation efficiency. *Mol Cell Toxicol*, *18*(1), 1-8. https://doi.org/10.1007/s13273-021-00171-4). mRNA tells the cell to produce the spike protein. The foundational technology for the vaccine was developed by Malone, et al. (Park, J. W., Lagniton, P. N. P., Liu, Y., & Xu, R. H. (2021). mRNA vaccines for COVID-19: what, why and how. *Int J Biol Sci*, *17*(6), 1446-1460. https://doi.org/10.7150/ijbs.59233) mRNA produced by the body is rapidly degraded in the body. The vaccine mRNA is modified to resist the degradation mechanisms of the body.(Schoenmaker, L., Witzigmann, D., Kulkarni, J. A., Verbeke, R., Kersten, G., Jiskoot, W., & Crommelin, D. J. A. (2021). mRNA-lipid nanoparticle COVID-19 vaccines: Structure and stability. *Int J Pharm*, *601*, 120586. https://doi.org/10.1016/j.ijpharm.2021.120586) Nevertheless, the mRNA vaccines are unstable. A special feature of mRNA is that even one change (strand break, or oxidation of the bases) in the long mRNA strand (typically between 1000 and 5000 nucleotides long) can stop translation.(Klauer, A. A., & van Hoof, A. (2012). Degradation of mRNAs that lack a stop codon: a decade of non stop progress. *Wiley Interdiscip Rev RNA*, *3*(5), 649-660. https://doi.org/10.1002/wrna.1124). This makes mRNA vaccines quite different from other vaccines in which small changes of the antigens do not necessarily have a measurable effect on their efficacy. Consequently, for mRNA vaccines, it is critical to monitor the integrity of the full molecule and that

the strict guidelines are followed when administering the vaccine. This is an impossible standard, given the large number of facilities and different level personnel administering the vaccine. The failure to set up routine quality assurance standards in the huge number of facilities administering the vaccine precludes an assessment of the appropriate handling of the vaccine to ensure stability**. Therefore, it is not correct to state that the vaccines are safe, as this aspect is not monitored.**

The mRNA component was to be degraded within 48 hours, but subsequent studies showed that it may persist for up to eight weeks in draining lymph nodes(Turner, J. S., O'Halloran, J. A., Kalaidina, E., Kim, W., Schmitz, A. J., Zhou, J. Q., . . . Ellebedy, A. H. (2021). SARS-CoV-2 mRNA vaccines induce persistent human germinal center responses. *Nature*, *596*(7870), 109-113. https://doi.org/10.1038/s41586-021-03738-2), (Röltgen, K., Nielsen, S. C. A., Silva, O., Younes, S. F., Zaslavsky, M., Costales, C., . . . Boyd, S. D. (2022). Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination. *Cell*, *185*(6), 1025-1040.e1014. https://doi.org/10.1016/j.cell.2022.01.018) and continue to direct cells to make spike protein. The spike protein spills into the blood (coming from both spike protein production and the natural killing of cells making the spike protein by the immune system). The amount of spike protein in the blood is found in almost all vaccinated people after 1 to 2 days and in some maybe thousands of times higher than the spike protein reached by natural infection. ((Röltgen K), 2022) In about 63% of the vaccinated the spike protein is still present after 7 days and may persist up to 28 days. After the second dose, the spike protein in the blood may bind to the antibody to form a complex and then attach to a cell surface and at normal blood barriers (blood vessels, kidney, blood brain barrier). The result is a type III hypersensitivity reaction. This results in inflammation and injury to the cells. If the reaction is at a joint, the result is arthritis. If the injury is directed against the kidney, it is glomerulonephritis. If the blood vessel is damaged the result is endotheliosis (inflammation of the cells lining the blood vessel or the blood vessel walls (vasculitis). Note due to antigen/antibody interaction, the spike protein may not be readily detectable in the blood. Evaluation of such injuries may take weeks to months and individuals receiving the vaccine should be alerted to these types of injuries, especially if they have an underlying immune condition. **Failure to evaluate these adverse reactions and correct for the inability to detect the spike protein in the blood prior to marketing makes it impossible to declare the vaccination safe for such individuals.**

At the heart of the vaccine is the spike protein. COVID-19 uses the spike protein to attach to and invade cells through the ACE2 receptor. The mRNA vaccines direct the body to make the spike protein, without making the entire virus, and thus initiate an immune response. The immune response is fundamentally different from natural infection. In natural infection the virus replicates in the upper respiratory tract (nose, nasopharynx, and throat). During this process the virus is attacked by the mucosal based immune system to make secretory IgA and simultaneously the virus is swallowed and initiates an IgM and then IgG response against the spike protein and other viral proteins. The mRNA vaccines only direct a response against the spike protein. The amount of spike

protein initiated by the viral vaccines is significantly higher in some patients (thousands of times higher than natural infection), without the IgM and IgA components. This high level of spike protein in the protein can initiate antigen/antibody interactions and type III immune reactions, especially after the second dose. **The failure to evaluate the inherent toxicity of the spike protein, and thus violate the prime principle of toxicology, precludes the statement that the vaccines are safe.**

This begs the essential question: is the spike protein inherently toxic and is this toxicity dependent on the dose (level or titer) achieved? The fundamental rule in toxicology is "the dose makes the toxin." (*The dose makes the poison concept* | toxicity. (2022, March 25). ChemicalSafetyFacts.Org. Retrieved April 30, 2022, from https://www.chemicalsafetyfacts.org/dose-makes-poison-gallery). The exact quote is from Paracelsus who said, "All things are poison, and nothing is without poison; only the dose makes a thing not a poison." Why is this important? **The failure to account for variation in dose and the difference in biological effect of the level of spike protein attained precludes a statement as to the safety of the vaccine for general use**. The failure to assess the effect of the spike dependent on the level obtained strikes at the very heart of the principle of toxicology. If the vaccine induces a spike protein level several thousand times that of a natural infection, then the biological effect, "the toxin", is likely to be profoundly different.

There are two issues at hand: the safety of the vaccine if it induced such a high level of spike protein and the efficacy of that antibody response. The spike protein is toxic to endothelial cells and to the blood brain barrier, without being part of the coronavirus. (Theoharides, T. C., & Conti, P. (2021). Be aware of SARS-CoV-2 spike protein: There is more than meets the eye. In *J Biol Regul Homeost Agents* (Vol. 35, pp. 833-838). Copyright 2021 Biolife Sas. www.biolifesas.org. https://doi.org/10.23812/theo_edit_3_21), (Dinetz, E. (2022). Case Series of Three Neurological Side Effects in Younger-Aged Individuals After Pfizer's mRNA Vaccine. *Cureus*, *14*(4), e23779. https://doi.org/10.7759/cureus.23779),(S, N. N., B, N. R., C, P., K, S. S., Ramakrishnappa, T., B, T. K., . . . Chandaragi, S. S. (2022). SARS-CoV 2 spike protein S1 subunit as an ideal target for stable vaccines: A bioinformatic study. *Mater Today Proc*, *49*, 904-912. https://doi.org/10.1016/j.matpr.2021.07.163) This is the exact condition found with mRNA vaccination**. Pfizer did not investigate the level of spike protein but only the neutralizing antibody response to the spike protein. The antibody response was equated to the effectiveness of the vaccine. This was never proven but taken as established fact**. Many researchers pointed out that natural infection induced a T cell immunity not achieved by vaccination and measurement of the antibody response was insufficient to demonstrate immunity.

The spike protein consists of 2 subunits, called S1 and S2. S1 contains the RBD or Receptor Binding Doman that binds the ACE2 receptor. It is the target of the mRNA vaccine. (Dinetz, E. (2022). Case Series of Three Neurological Side Effects in Younger-Aged Individuals After Pfizer's mRNA Vaccine. *Cureus*, *14*(4), e23779. https://doi.org/10.7759/cureus.23779) (, N. N., B, N. R., C, P., K, S.

S., Ramakrishnappa, T., B, T. K., . . . Chandaragi, S. S. (2022). SARS-CoV 2 spike protein S1 subunit as an ideal target for stable vaccines: A bioinformatic study. *Mater Today Proc*, *49*, 904-912. https://doi.org/10.1016/j.matpr.2021.07.163) S1 is removed from the spike protein to allow activation of the S2 subunit which will allow the virus to fuse with the cell. The S1 subunit is then released into the circulation and ends up in an immune cell called a macrophage. In normal time, the job of the macrophage is to clean up the mess left after an immune response. But if the macrophage eats the S1 subunit, like Dr. Jekyll and Mr. Hyde, it transforms from short-lived cell that controls inflammation (the Dr. Jekyll) to a monstrous Mr. Hyde, that lives for a long time and initiates a vascular inflammatory response (Shirato, K., & Kizaki, T. (2021). SARS-CoV-2 spike protein S1 subunit induces pro-inflammatory responses via toll-like receptor 4 signaling in murine and human macrophages. *Heliyon*, *7*(2), e06187. https://doi.org/10.1016/j.heliyon.2021.e06187). In turn, this initiates an inflammatory response against the endothelial cells, the cells that line the blood vessels, and results in an endothelialitis (Rotoli, B. M., Barilli, A., Visigalli, R., Ferrari, F., & Dall'Asta, V. (2021). Endothelial Cell Activation by SARS-CoV-2 Spike S1 Protein: A Crosstalk between Endothelium and Innate Immune Cells. *Biomedicines*, *9*(9). https://doi.org/10.3390/biomedicines9091220) and vasculitis (Kar, B. R., Singh, B. S., Mohapatra, L., & Agrawal, I. (2021). Cutaneous small-vessel vasculitis following COVID-19 vaccine. In *J Cosmet Dermatol* (Vol. 20, pp. 3382-3383). https://doi.org/10.1111/jocd.14452).

Since the 1950s and the disastrous experience with thalidomide that was used during pregnancy, along with knowledge of the rapid tissue development that occurs with pregnancy, the adage has been to avoid every known noxious substance (such as alcohol and smoking) during pregnancy. As defects may be subtle and take years to manifest, normal vaccination evaluation requires years of follow up. **During the Pfizer safety evaluation, no pregnancy evaluation is done. It was impossible to declare the vaccine safe for pregnant women.** Later studies purported to show the safety of vaccination, but a close evaluation of the data showed a high abortion rate, if the vaccine was delivered before the 20th week(Shimabukuro, T. T., Kim, S. Y., Myers, T. R., Moro, P. L., Oduyebo, T., Panagiotakopoulos, L., . . . Meaney-Delman, D. M. (2021). Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. *N Engl J Med*, *384*(24), 2273-2282. https://doi.org/10.1056/NEJMoa2104983). Yet, many women were not informed of the lack of safety evaluation. Reports in VAERS show infant death following maternal vaccination if the infant was breast fed.

So, is the vaccine safe? How would one know? There is no testing of penetration of the blood-brain barrier. There is no testing of pregnant women. There is no testing as to whether the spike protein itself may have noxious effect. The failure to indicate PEG and emulsifiers as components of the vaccine, certainly make it unsafe for those who have such allergies.

COVID-19 was declared to be an emergency. This was used to justify the lifting or sidestepping of normal safeguards that dictate vaccine development. As our understanding of the disease evolved,

it rapidly became evident that it was only a risk to the elderly and the obese. We were promised a vaccine to prevent disease and thereby protect our vulnerable population. This was an admirable goal if the vaccine prevented infection. During the Pfizer Efficacy Trials , it unequivocally demonstrated that the vaccine did not prevent infection. Of the 40,000 plus participants in the trial, only 170 were evaluated for efficacy of the vaccine. Of these 170 in primary efficacy results (Table 5 Page 36), 8 were fully vaccinated and developed the disease, while 162 of the placebo group developed the disease.

During the trials, many patients were unblinded. Given the small number of patients evaluated for efficacy of the vaccine, any unblinding is likely to have altered the results. During the trial, approximately 400 participants did not receive the second dose, and another 400 participants were not fully vaccinated. (Table 48 Page 145) The explanation for this is incomplete. It suggests that many participants had sufficient adverse reactions to drop out of the trial or avoid the second dose. The small number of evaluated patients, the lack of clarity over unblinding and its effect on evaluation of efficacy strongly suggests that at best, the results are compromised and an example of self-deception, and at worst, an overt act of fraud. This raises the additional question: of the 20,000 placebo participants, only 162 developed disease! How much of an emergency could this virus be?

During the trials it was also evident that between 5% and 20% of the population was already infected with COVID-19. This large number of infections indicated that lockdowns would be ineffective at controlling the disease. In a recent interview with Dr. Anthony Fauci, he acknowledged this fundamental truth of immunology and epidemiology. Dr. John Ioannidis, an eminent epidemiologist from Stanford University, early in the pandemic, told us that at least 5% of the population was already infected (and by implication, any lockdown would be ineffective). The three main authors of the Great Barrington Declaration, eminent and world-renowned epidemiologists told us so, and how best to address the issue.

The conclusions are evident. There are two types of sins: the overt sin of commission and the occult sin of omission The overt sin of commission is blatant lying. The occult sin of omission is more subtle but aptly summed up as “lying with the truth”. Both were committed by Pfizer, Moderna and public health authorities.

There was no evaluation of vaccine penetration on the brain or distant organs, such as the ovary, or whether it passed through the placenta to the baby in the mother’s womb, or in her breast milk to her infant. The evaluation of spike protein in the blood with the formation and effect of high levels of IgG antibody as a cause of Type III immunological injury was never done.

The failure to point out the deficiencies of the study that were likely to alter the results was never done. In the absence of such evaluation, it is impossible to conclude that the vaccine was safe. The vaccine was never demonstrated to be effective or efficacious. The vaccine did not prevent disease.

And the disease itself was nowhere near as big a threat to population as promoted by public health authorities and echoed in the chambers of the media.

Report 7: "COVID-19 Vaccines and Pregnancy: Risky Business" – Beth Burgos, MD – Team 1.

To date there have not been any human clinical trials conducted by a COVID-19 vaccine pharmaceutical company to determine if vaccines are safe during pregnancy or while breastfeeding. All Emergency Use Authorizations (EUA's) exclude pregnant women and no COVID-19 vaccine has been approved for use during pregnancy. Astonishingly, however, many professional medical organizations have strongly advocated for their use during pregnancy despite the lack of any safety data. Unfortunately, as more pregnant women have been vaccinated, serious adverse events are being exposed in both Pfizer documents and in the Department of Defense (DOD) medical database.

Thanks to a court ordered release of confidential Pfizer documents (the FDA wanted these documents sealed for 75 years) we have learned that pregnant women and breastfeeding mothers were excluded from phase 1, 2 and 3 of the human trials. One recently released Pfizer document lists 21 groups of people who were excluded from all phases of the Pfizer trials and specifically singles out "women who are pregnant or breastfeeding" as not able to participate in any of the trials https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sample-crf.pdf (Annotated Study Book for Study Design: C4591001 Study Design Version: 11.0, 2020, Page 33 item 2.h 11, exclusion 11A00 under exclusion criteria).

Despite this, organizations such as the American College of Obstetrics and Gynecology (ACOG) and The Society for Maternal-Fetal Medicine (SMFM) are strong advocates for vaccinating pregnant and lactating women. In an unprecedented manner, ACOG persistently advocated for pregnant women to get vaccinated while acknowledging in their clinical guidelines that "none of the COVID-19 vaccines approved under EUA have been tested in pregnant individuals." https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care So how could they possibly be promoting an experimental and untested vaccine for pregnant women? As it turns out their clinical recommendations are based on a faulty study conducted on a few dozen rats in France.

Before any research trials can be performed on human pregnant women, a new drug must first be tested on pregnant animals. These are called Developmental and Reproductive Toxicity or (DART) studies. In ACOG's clinical guidelines, they stated that the "DART studies for the Pfizer-BioNTech COVID-19 vaccine have been reported in Europe... According to the report animal studies using the Pfizer/BioNTech COVID-19 vaccine do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition, or postnatal development." https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care

So, we see that their confidence in the safety of the Pfizer vaccine is based solely on animal studies. Given the extreme importance of studying the effects of a new vaccine technology on pregnant women and their offspring; one would expect this study to be conducted by independent researchers using a robust design that answers fundamental questions. Questions like were there any congenital abnormalities or developmental issues in the offspring and were there any long-term effects on fertility?

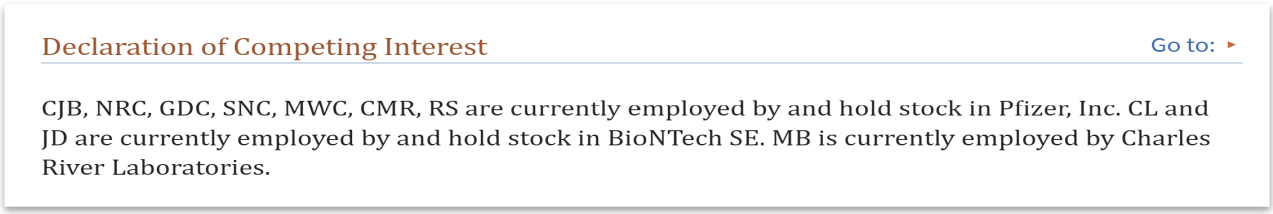
After a review of this study, it is astounding to discover that it was performed on a mere 44 rats and for a length of only 42 days! https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8163337/ To their credit it turns out that rats are the perfect mammal to do pregnancy studies on because they only need 21 days from conception to delivery. Half of the rodent pregnancies were terminated at day 21 via cesarean section and the fetuses were removed from the mother. All were euthanized and then anatomically studied. The other half were allowed to deliver naturally and then were monitored until they were weaned at 21 days of age when the rest were euthanized. This is long before any developmental issues could have been observed in the offspring and precludes any long-term safety or fertility studies of the mothers or their offspring. The effects on fertility in this study were determined by dissection and examination of the ovaries of the mother rats who were fully mature at the time of vaccination.

After this 42-day study on 44 pregnant rats they concluded that there were "no effects on female fertility and prenatal and postnatal offspring development in rats with BNT162b2, mRNA-based COVID-19 vaccine." Thus, supposedly, the prerequisite for a DART study was complete. However, there are at least two glaring problems with this study.

First, it does not fulfill the requirements of a DART study, which is "to detect any effects of a drug within a complete reproductive cycle as relevant to humans: from initial conception to reproductive capacity in the next generation." There is no way to know if any adverse effects on the development of those newborn rats occurred, let alone to know if their reproductive capacity (fertility) was altered.

Second, there was a significant conflict of interest with the studies' investigators. The "Declaration of Competing Interest" disclaimer at the bottom of the publication reveals that nine out of ten of the authors of the study were employed by and held stock in either Pfizer or BioNTech. There is no way these investigators could be unbiased; they all had a vested interest in a positive outcome for vaccine trials to move forward. Any negative result would have put a complete halt to any human clinical trial. It would seem they hid this fact as best they could. These are the authors listed at the top of the article: Christopher J. Bowman, Marie Bouressam, Sarah N. Campion, Gregg D. Cappon, Natasha R. Catlin, Mark W. Cutler, Jan Diekmann, Cynthia M. Rohde, Rani S. Sellers, and Claudia Lindemannd.

There is a disclaimer listed at the very bottom on the last page of the article. It only uses initials, so it is easy to miss. Compare the initials from the disclaimer at the very end to the authors listed at the beginning.



Declaration of Competing Interest Go to:

CJB, NRC, GDC, SNC, MWC, CMR, RS are currently employed by and hold stock in Pfizer, Inc. CL and JD are currently employed by and hold stock in BioNTech SE. MB is currently employed by Charles River Laboratories.

Despite this, pregnant women in the United States were encouraged to get vaccinated based on an extremely limited DART animal study that had obvious conflicts of interest. These women, likely out of fear of COVID-19 and with the reassurance of the CDC, FDA, and medical professional organizations, received the vaccine. By the end of 2020 and into 2021, thousands of pregnant women received vaccinations during pregnancy with no EUA approval.

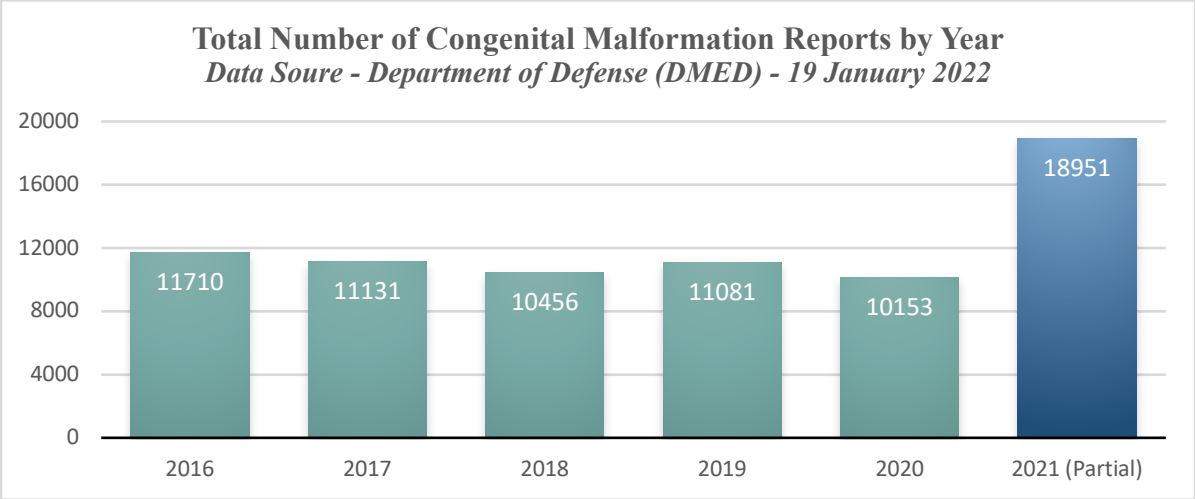
It is notable that even with all the organizations promoting vaccination during pregnancy, the World Health Organization recommended against it until at least January of 2021. Now they don't recommend against it but instead recommend that pregnant women should weigh the potential risks against the benefits, while simultaneously admitting that there is no long-term safety data available. Either way, since the vaccines have been broadly deployed a great deal of data has been compiled.

So, what does the "safety data" that has been collected on mRNA COVID-19 vaccinated pregnant women show? The FDA requires Pfizer to collect any publicly available data on adverse events related to vaccination once it goes to market. Confidential document (5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports) contains case reports for the first 68 days of vaccine rollout (from 12/20/2020 to 2/28/2021). The section covering pregnancy and lactation on pages 12-13, reveals that 20% of the 413 reported cases of adverse events were "serious." These included 25 miscarriages, 5 fetal deaths as well as uterine contractions during pregnancy, preterm deliveries, premature rupture of membranes and fetal growth restriction. Also included were serious and less serious adverse side effects of breast-fed babies that included infantile vomiting, fever, rash, agitation, and allergy to the vaccine. There were also 6 cases of women having adverse events who received COVID-19 vaccine while breastfeeding; some of these include paresis (partial paralysis), suppressed lactation, breast pain, migraines and breast milk discoloration. Pfizer's response to the above alarming data was, "There were no safety signals that emerge from the review of these cases of use in pregnancy and while breastfeeding."

Probably the largest and most reliable health database on overwhelmingly healthy and fit military personnel is collected by the Department of Defense (DoD). This has recently been exposed by three whistleblowers represented by Attorney Thomas Renz. https://health.mil/Military-Health-

Topics/Combat-Support/Armed-Forces-Health-Surveillance-Division/Data-Management-and-Technical-Support/Defense-Medical-Epidemiology-Database They observed disturbing evidence of dramatic increases in serious medical conditions among military personnel in 2021, correlating directly with the roll out of COVID-19 vaccines. Among the numerous conditions listed are congenital malformations.

The rise in congenital malformations increased dramatically from a baseline rate of 10,906 cases per year, to 18,951 for only part of the year in 2021.



Having shown that there is significant risk involved in taking the vaccine when pregnant, let's now consider the supposed benefits touted by the NIH, CDC and others.

The NIH says "The COVID-19 Treatment Guidelines Panel recommends against withholding treatment for COVID-19 and SARS-CoV-2 vaccination from pregnant or lactating individuals because of *theoretical safety concerns (AIII)*" (emphasis added). The (AIII) at the end is important. "A" indicates they strongly recommend this and "III" indicates the lowest available rating for evidence used, which is "Expert opinion." https://www.covid19treatmentguidelines.nih.gov/special-populations/pregnancy The CDC says, "Limited information suggests that pregnant women with COVID-19 might be at increased risk for severe illness compared with nonpregnant women". https://www.cdc.gov/mmwr/volumes/69/wr/mm6944e3.htm The word "suggests" has a specific meaning in this statement: "The word "suggested" is used when the strength and direction of the results are unified, but results do not achieve statistical significance." https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/systematic-review-process.html

In layman's terms, the NIH is saying that they strongly suggest that pregnant women be vaccinated for COVID-19 based upon the recommendation of "expert opinion" from groups such as ACOG and SMFM alone, not based on any reliable evidence from one or more randomized trials without major limitations. And we know that ACOG's "expert opinion" relied heavily upon the limited Pfizer-BioNTech DART study. The CDC is acknowledging that there is limited information supporting the claim that pregnant women with COVID-19 might be at increased risk for severe

disease compared with non-pregnant women because the study results claiming this risk cannot prove statistical significance to back up that claim.

The evidence is clear that the potential risks of pregnant women getting vaccinated with the new mRNA COVID-19 vaccines far outweigh the touted yet unproven benefits. The alarming safety signals revealed in the Pfizer documents and DOD database along with the lack of any long-term safety data overwhelmingly leads to the conclusion that getting vaccinated during pregnancy is a Risky Business… *Risky* for the people getting vaccinated and big *Business* for the pharmaceutical industry.

Report 7: "Why Was the Pfizer COVID-19 Vaccine Recommended for Use in and Administered to Children When It Was Not Tested in That Age Group?" – Team 1.

Thanks to a court ordered release of confidential Pfizer documents we have learned that 21 groups of individuals were excluded from phase 1, 2 and 3 of their human trials. Children under the age of 18 were one of these excluded groups. https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sam-ple-crf.pdf (Annotated Study Book for Study Design: C4591001 Study Design Version: 11.0, 2020, Page 33).

Despite this exclusion criteria, many children were given the vaccine anyway. Why was the vaccine recommended for use in and administered to children when it was never tested in that age group? In Pfizer document 2.5.4 Summary of Clinical Safety, dated May 5, 2020, it states on page 294, "Further study of pediatric use of the vaccine and/or immunobridging study will be undertaken to characterize the vaccine response in children." Immunobridging is the extrapolation of the safety and efficacy results of one study group to another. One must ask then, can the results of studies done only on individuals over the age of 18 be extrapolated to children under 18 with any degree of certainty?

The Pfizer COVID-19 vaccine was first authorized for Emergency use only in healthy adults aged 19-80 on December 11, 2020. In the three months following the EUA, Pfizer reported 175 cases of adverse events in adolescents and children under age 17. Thirty-four of these cases were in children under the age of 12.

The Vaccine Adverse Events Reporting System (VAERS) database is maintained by the FDA. The VAERs database relies on self-reported information and because there is no systematic way to gather data for every possible case of an adverse event that occurred, it is well known that adverse events are largely underestimated by the methods in current use. Keeping in mind that the VAERS data represents only a fraction of the actual adverse events, what did the data show in the children who first received the vaccine without any authorization? In the United States alone, in 2021 there were 313 serious events reported in children aged 6-17 resulting in 37 deaths. There was also 1 report of a serious adverse event in a child aged 3-5 which resulted in the death of that child.

Why would any Pediatrician recommend that their patients be vaccinated prior to any vaccine trials in children? It seems that they are viewing this new mRNA vaccine as similar to all other childhood vaccines and even recommend combining it with the other well established and thoroughly tested childhood immunizations. Observe what the American Academy of Pediatrics (AAP) recommends. This information appears on the American Academy of Pediatrics website: (*Pediatrics* (2021) 148 (2): e2021052336. https://doi.org/10.1542/peds.2021-052336)

> "The American Academy of Pediatrics (AAP) recommends the following related to coronavirus disease 2019 (COVID-19) vaccine in children and adolescents:

- *Given the importance of routine vaccination and the need for rapid uptake of COVID-19 vaccines, the AAP supports coadministration of routine childhood and adolescent immunizations with COVID-19 vaccines (or vaccination in the days before or after) for children and adolescents who are behind on or due for immunizations (based on the CDC and AAP Recommended Child and Adolescent Immunization Schedule) and/or at increased risk from vaccine-preventable diseases."*

In these recommendations which were published in August of 2021, the AAP supports co-administration of routine childhood and adolescent immunizations with COVID-19 vaccines. At that point, the Pfizer vaccine had never been formally tested in circumstances where it was administered simultaneously with other routine child and adolescent vaccines.

Could the COVID-19 vaccine alter the ability of the other vaccines to produce adequate immunity to the diseases that they are targeted to prevent such as measles, mumps, rubella, etc. when co-administered with COVID-19 vaccines?

On January 16, 2022, the peer reviewed journal of Influenza and Other Respiratory Viruses ((Influenza Other Respiratory Viruses) 2022 Jan; 16(1): 3–6. Published online 2021 Oct 3. doi: (10.1111/irv.12917) reported:

"The US CDC has recently recommended that routine vaccines could be co-administered with authorized COVID-19 vaccines, in order to facilitate the catch-up of missed immunizations. *This public health decision was not based on new clinical trial evidence* but on the accumulated safety experience of the currently authorized COVID-19 vaccines in millions of recipients, *albeit over a relatively short time frame*, and the previous experience of safe and effective administration of multiple antigens simultaneously.
Safety data on the coadministration of influenza and COVID-19 vaccines are currently being acquired.

As COVID-19 vaccines are further studied and potentially authorized for young children and infants, careful consideration and evidence for safe and effective coadministration with influenza and other routine vaccines is in children also warranted. As the available data to date indicate that coadministration of vaccines is a viable approach, there is benefit in continuing to generate more data to support this as it would facilitate the catch-up of missed vaccinations and would also expedite an efficient outcome for dual protection against influenza and COVID-19."

Note that the endorsement of co-administration of COVID-19 vaccine and other routine childhood and adolescent vaccines was published by the American Academy of Pediatrics in August 2021 while in the article published in January 2022 in the Influenza and Other Respiratory Viruses journal

states that sufficient data *does not yet exist* to establish the safe and effective coadministration with influenza and other routine vaccines in children and that more data is needed.

The same article also states that the CDC recommendation is based upon "previous experience of safe and effective administration of multiple antigens simultaneously". While it may be true that other antigens can be administered safely and effectively such as the combination vaccine of measles, mumps, and rubella, the mRNA vaccines employ a completely different mechanism in the development of antigenicity than any other vaccine that has been developed to date. Can we really assume that the same safety and effectiveness profile exists for this brand-new mRNA vaccine when compared to those in the past? It seems to me that one is comparing apples to an orange.

The families of 38 dead children cry out for a stop to this unscientific comparison.

Report 8: "Even Big Pharma CEOs recognized that not everyone could be vaccinated - so why Vaccine Mandates?" by Chris Flowers, MD – Team 1.

Recently, Project Veritas revealed that the CEO of AstraZeneca, Pascal Soriot, told his company in a Zoom call in Dec 2020 that not everyone could be vaccinated; Soriot identified the immune-compromised and people with multiple sclerosis as examples if those who should not be vaccinated with mRNA vaccines. He raised this issue in the context of explaining that the company AstraZeneca had a great opportunity in the marketplace — to make antibody treatments for those vulnerable populations, treatments, that is, which could give protection to those who should not be vaccinated. (https://www.projectveritas.com/news/astrazeneca-source-recording-from-2020-shows-ceo-pascal-soriot-saying).

Project Veritas broke the story on April 19, 2022, where Soriot admits that immunocompromised populations should not consider the AstraZeneca vaccine safe.

YouTube also has this incriminating video - https://www.youtube.com/watch?v=Lk0OJwZwE5g).

Soriot's comments were contradictory to remarks about the safety of the vaccine for immunocompromised people made by the World Health Organization (WHO) at the time. More recently, on March 16, 2022, a Health Advisory from the WHO restated the assertion that the vaccine was SAFE for immunocompromised individuals. (https://www.who.int/multi-media/details/who-press-conference-on-covid-19-ukraine-and-other-emergencies---16-march-2022 - Time marker: 39 mins). Those statements appear to give false assurance.

There have been serious problems with the AstraZeneca vaccine even for the general population. AstraZeneca is the maker of one of the main COVID vaccines used in Europe, which along with Johnson and Johnson's (Janssen vaccine) has been plagued with reports of the vaccines' causing small vessel blood clots. (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html#ingredients)

In admitting the fact that vaccine-induced immunity is not viable for immunocompromised patients, AZ saw the commercial opportunity to develop and manufacture monoclonal antibodies against the S (SPIKE) protein.

This is the important argument that they make, in stark contrast to the CDC and FDA pronouncements in the USA where vaccine mandates were National Policy, that you cannot produce antibodies to a vaccine if you are immunocompromised and need to have a different source of antibodies.

Why should this matter in the US?

AstraZeneca (AZ), like Johnson and Johnson (J&J), used a conventional approach of a modified viral vector (rather than using mRNA) for producing immunity. AZ recognized the issues this would create with patients whose natural immunity was depressed due to illness or to chemotherapy drugs (a state known as being 'immunocompromised').

So why weren't Monoclonal antibodies the first line of attack against COVID?

Steps were taken by several States, who targeted their vulnerable populations with protective efforts (such as closing visits to care homes in the early days) and purchased monoclonal antibodies to use in the fight against COVID. Vaccines were not available until late November 2021.

Patients with a compromised immune system could have their immunity provided by externally administered antibodies.

Antibodies from patients who had recovered from COVID, known as Convalescent Plasma was first approved by the FDA in August 2020. (https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment) In November, 2021, the FDA approved the first two monoclonal antibody treatments manufactured by Regeneron Pharmaceutical Inc. (Casirivimab and Imdevimab) (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19)

Subsequently monoclonal antibodies became one of the important mainstays of treatment in a number of US States, where the priority was to protect the vulnerable population, rather than to make use of a 'one size fits all' vaccine treatment.

So why mandate a vaccination for 100% of the population if vaccination is NOT effective for immunocompromised patients?

If the CEOs of Vaccine Manufacturers can recognize the lack of effectiveness in part of the population, why do the CDC/FDA as well as W.H.O. continue to advocate for additional boosters for these patients? In view of the serious side effects of the mRNA vaccines already known, why are they still being mandated?

The only conclusion that I can come to is that vaccine mandates are both unwise and downright wrong.

Recording of AstraZeneca CEO Pascal Soriot ‘Millions of [Immunocompromised] People Can’t Be Vaxxed': https://www.youtube.com/watch?v=Lk0OJwZwE5g

Report 9: "PFIZER VACCINE: FDA Fails to Mention Risk of Heart Damage in Teens" by Chris Flowers, MD – Team 1.

BOMBSHELL: FDA MUST HAVE KNOWN THAT MYOCARDITIS IN TEENS WAS A RISK WHEN THEY ISSUED THE EMERGENCY USE AUTHORIZATION THAT DID NOT MENTION IT.

In a paper published in pre-print last week (25th March 2022) in the Journal of Pediatrics https://www.jpeds.com/article/S0022-3476(22)00282-7/fulltext#%20 Shauer et al. from the Seattle Children's Hospital at the University of Washington:

Report on their findings of 35 cases of myocarditis in children within one week after receiving the second dose of the Pfizer mRNA vaccine.

They present the evolution of changes on Cardiac MRI (Magnetic Resonance Imaging)

1) Myopericarditis has emerged as an important adverse event following COVID-19 mRNA vaccination, particularly in adolescents. This affects both the lining of the heart (pericardium) and the cardiac muscle (myocardium) itself. [Ref: Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, et al. Morbidity and Mortality Weekly Report Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices-United States, June 2021 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8312754/]

The report acknowledged the risks of myocarditis post vaccine, but still recommended vaccination to everyone.

This initial report established the serious problem of myopericarditis in adolescents following MRNA vaccination was published in June 2021.

June 2021 was one month AFTER the FDA received the priority review for an EUA for 16 years and older to receive the mRNA vaccine. [125742_S1_M1_priority-review-request-1 (released March 24, 2022)]

REQUEST FOR PRIORITY REVIEW

COVID-19 Vaccine (BNT162, PF-07302048)

BLA 125742

MAY 2021

2) This timeline raises grave questions about what the FDA knew and when they knew it, since the results of this paper would have been 'peer reviewed' some months BEFORE the May 2021 publication took place.

That is, the risk of heart damage to teenagers would have been part of the medical knowledge base BEFORE the emergency use authorization for teenagers was issued by the FDA in June 2021.

The finding of heart damage in teenagers, thus, would have been available to the FDA at the time of the May 2021 EUA application.

The FDA did not disclose the risk of these harms to the general public at that time.

3) The Emergency Use Authorization itself in May 2021 does NOT mention any risk of myocarditis in adolescents, even though the 16+ age group was being filed for in this EUA.

An FDA committee reviews and then grants the EUA. The FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss newly available data for the currently available COVID-19 vaccines.

We [the volunteers in the Pfizer War Room documents review group Team 3] have not seen any discussions of the issues [of myopericarditis] by the FDA approvals committee as they are not available to the public.

There is no press release from the FDA about the approval of the May 2021 EUA application, but in an August 2021 press release https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine the FDA report that myocarditis is a known side effect and a warning is in the data sheet of the newly authorized commercial vaccine (COMIRNATY).

See below from the press release.

> Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information includes a warning about these risks.

Thus, it appears that the Food and Drug Administration should or must have known about elevated risk of heart damage to teenagers in a peer-reviewed publication and failed to disclose it to the public when announcing the Emergency Use Authorization. (We don't actually have any data on this. This is an educated assumption only.)

Due to the lack of disclosure by the FDA of the known harms, the parents who chose to have their teenagers vaccinated with mRNA vaccines, therefore, could not have made use of fully informed consent. That was remedied a few months later in the data sheet of the commercial (COMIRNATY) vaccine, as described in the press release above.

Dr. Chris Flowers MBBS, FRCR, FSBI is a retired Associate Professor of Radiology at University of South Florida. He was previously an Associate Professor of Radiology and Biomedical Imaging at University of California, San Francisco. He is also a retired academic cancer radiologist, author, and scientific paper reviewer for multiple radiology journals.

Report 10: "Secret Documents: How Pfizer Covered Up a Flood of Adverse Events" by Stevan Douglas Looney, JD

I am a civil trial and appellate attorney in New Mexico, with experience litigating complex matters. My prior essay for DailyClout.io regarding the Pfizer War Room Document Review — for which I volunteer as one of 250 attorneys — argued that the documents clearly show evidence of fraud on the part of Pfizer. The latest tranche of documents, released on April 1, 2022, show an equally dramatic revelation: Pfizer *knew* by February of 2021, that there were had been 'a large number of adverse events' in the three months prior.

Pfizer also realized that these adverse events were so abundant — and they expected so many more in the months to come — that they advised the FDA that they would hire 2400 additional staffers to deal with the paperwork and data processing they expected due to the anticipated volume of adverse events!

I reviewed the April 1, 2022, tranche of Pfizer documents the FDA produced pursuant to a federal court order. A document produced on November 17, 2021, was also "reissued" on April 1, 2022. At first glance they appear identical, but they are not. Importantly, information redacted (deleted) from the document produced in the March 2022 production, was included in the April 1, 2022, production. This information is quite telling, and some conclusions can be drawn.

The document produced on November 17, 2021, is titled "5.3.6 postmarketing experience.pdf" (November 17, 2021 (984 KB), https://www.phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). That same document in the April 1, 2022, production is titled "reissue_5.3.6 postmarketing experience.pdf". (April 1, 2022 (958 KB), https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf). The word "reissue" is absent in the November 2021 version. That made me curious, so I did a comparison of the two documents. Here is what one will find on page 6. (The "Bates" number in both documents in the bottom, right-hand corner is "FDA-CBER-2021-5683-0000059.")

The lengthy paragraph on page 6 of the November 2021 document concerns adverse events reports received by Pfizer as of February 28, 2021. The third sentence of that paragraph in both documents reads: "Due to the large number of spontaneous adverse events reports received for the product [i.e., BNT162b2], the MAH [Marketing Authorization Holder] has prioritized the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity."

This paragraph ends: "Pfizer has also taken a [sic] multiple actions to help alleviate the large increase of adverse event reports." Think about that sentence.

*"This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately **600** additional full-time employees (FTEs). More are joining each month with an expected total of more than **1,800** additional resources **by the end of June 2021** [emphasis added]."* Also on page 6, under the heading "3. RESULTS", at "3.1.1 General Overview", Pfizer discloses in the document produced on April 1, 2022, what it redacted from the same document produced in November of 2021. What Pfizer had produced in April 2022 to take the place of the redacted document in November 2021 document was the fact that for the three-month period beginning December 1, 2020, to February 28, 2021, Pfizer shipped "approximately **126,212,580** [emphasis added] doses of [the FDA emergency use authorized] BNT162b2″ worldwide.

The 126,212,580 figure is redacted in the document produced in November 2021 but is included in the "reissue" document of April 1, 2022.

Likewise, the new, full-time 600 and 1,800 employees, amounting to a total of 2,400 full-time employees, hired to deal with all the anticipated adverse events, are included in the document produced on April 1, 2022, but had been redacted from the same document the FDA had produced in November of 2021. Why the foregoing data were redacted, but then disclosed, we do not know, yet We do know that the redacted information is damning. What did we learn by comparing the two documents?

First, between December 1, 2020, and February 28, 2021, a period of three months, "a large number of spontaneous adverse events reports" were made to Pfizer regarding the administration to humans of the BNT162b2 "vaccine" for which the FDA had provided emergency use authorization (EUA).

Second, by February 28, 2021, (the date of the document) Pfizer knew that by June of 2021 it would hire at least an additional 2,400 full-time employees to process the adverse events reports Pfizer was receiving. (Appendix 1 to these documents is a list of 1,290 adverse events of special interest (AESI) received in connection with the BNT162b2 "product." Based upon my research to date, I have found no evidence that these AESI were disclosed publicly prior to November of 2021.)

Lastly, and incredibly, despite having this information, on August 23, 2021, the FDA granted continued EUA status for the BNT162b2 "vaccine" and also approved Bio-N-Tech/Pfizer's product known as COMIRNATY. Notably, according to the FDA, both the EUA BNT162b2 and the "approved" COMIRNATY are identical and interchangeable products. Thus, it is reasonable to conclude that COMIRNATY also causes "a large number of spontaneous adverse events," including the adverse events and AESI listed in Appendix 1 to these documents.

In sum, Pfizer did not only apparently commit fraud, but they also compounded the fraud by hiring 2,400 full-time employees to deal with the flood of adverse events that they expected – and yet they told no one about this publicly.

I will continue to issue analyses of these historic documents.

Mr. Looney is a civil trial and appellate attorney with 42 years of experience, concentrating on complex matters. Mr. Looney is licensed in New Mexico and practices in all its courts, as well as the United States District Court for the District of New Mexico, the Tenth Circuit Court of Appeals, the US Tax Court and the US Supreme Court. Mr. Looney served in the U.S. Army as an infantryman from 1970-1972, assigned to the 82nd Arbrn. Div.

Report 11: "Missing – 50 Pregnant Women from Pfizer Clinical Trials" by Cindy Weis.

In the first batch of Pfizer documents released, the volunteer group I am a part of was assigned to review Document 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports. Because there were a significant number of Adverse Events reported in pregnant women, I decided to pay close attention to future documents regarding vaccine effects on pregnancy.

According to the Pfizer Clinical Protocol Document, women who are pregnant or breastfeeding were to be excluded from the vaccine trials. They were not allowed to begin them if pregnant:
Page 42
Exclusion Criteria
11.Women who are pregnant or breastfeeding.

And, if they became pregnant during the study, they were withdrawn from receiving further vaccinations:

"Stopping Rule Criteria for Each BNT162 Vaccine Candidate:"
Pg 65
8.2.6. Pregnancy Testing
Pregnancy tests may be urine or serum tests but must have a sensitivity of at least 25 mIU*mL. Pregnancy tests will be performed in WOCBP at the times listed in the SoA, immediately before the administration of each vaccine dose. A negative pregnancy test result will be required prior to the participant's receiving the study intervention. Pregnancy tests may also be repeated if requested by IRBs*ECs or if required by local regulations. In the case of a positive confirmed pregnancy, the participant will be withdrawn from administration of study intervention but may remain in the study. (https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf)

The Clinical Overview document below lists 50 women who were a part of the Clinical Trials that reported pregnancies.

As I read it, 16 of them withdrew from the study due to pregnancy. The wording is confusing, but it appears that at least the remaining 34 women "continue to be followed for pregnancy outcomes." It could also be construed to mean all 50 are to be followed. See below:

2.5 Clinical Overview Document
Pg. 320, 321
2.5.5.7.2. Pregnancies
At the time of the data cutoff date (13 March 2021), a total of 50 participants who had received BNT162b2 had reported pregnancies, including 42 participants originally randomized to the BNT162b2 group and 8 participants originally randomized to the placebo group who then received BNT162b2. In total, 12 participants (n=6 each in the randomized BNT162b2 and placebo groups)

withdrew from the blinded placebo-controlled vaccination period of the study due to pregnancy, and 4 participants originally randomized to placebo who then received BNT162b2 withdrew from the open-label vaccination period due to pregnancy (Table 54). These participants continue to be followed for pregnancy outcomes. No births have been reported from individuals who have become pregnant in Study C4591001 as of the time of this submission. (https://www.phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf)

According to the Clinical Protocols Document these women should be followed for a minimum of 6 months from their last visit, ostensibly the date when they were withdrawn:

4.4. End of Study Definition
A participant is considered to have completed the study if he/she has completed all phases of the study, including the last visit. Note that participants enrolled in Phase 1 in groups that do not proceed to Phase 2/3 may be followed for fewer than 24 months (but no less than
6 months after the last vaccination).
The end of the study is defined as the date of the last visit of the last participant in the study.

Using Abstractor [https://vaccines.shinyapps.io/abstractor/], a front-end search tool that searches all released Pfizer documents, I did a search using the terms “pregnant and pregnancy” and yet found no updated information on these women and their pregnancy outcomes.

As more information on the dangers to pregnant women from the mRNA vaccines surfaces, some of which the manufacturers had at their disposal very early on, I feel it is imperative that we hear the stories of these 50 women and their babies.

Report 12: "Were We Lied to by the FDA?" by Stevan Douglas Looney, JD

What's the difference between Pfizer's FDA approved COMIRNATY and the emergency use authorized "vaccine?"

Only the law, not science, says the FDA.

Were we lied to by the U.S. Food and Drug Administration (FDA) and the media when they told us that, if we received the Pfizer "vaccine" after August 23, 2021, we, along with our children, would receive the FDA-approved COMIRNATY? Unfortunately, the answer is a clear "yes," and the FDA itself tells us so.

On August 23, 2021, the FDA issued two letters to Pfizer, Inc. One letter (https://www.armstrongeconomics.com/wp-content/uploads/2021/08/FDA-Letter-Final_Pfizer-LOA-to-issue-with-BLA-approval-08.23.21_v2.pdf) was addressed to Pfizer at its office in Collegeville, Pennsylvania, and concerned the FDA's extension of the emergency use authorization (EUA) of "Pfizer-BioNTech COVID-19 Vaccine," i.e., the experimental mRNA gene therapy referred to in clinical trials (which are ongoing) as BNT162b2.

The other letter (https://www.fda.gov/media/151710/download) was addressed to both BioNTech Manufacturing GmbH (BNT) and to Pfizer, Inc., at an address in New York, New York, and concerned the FDA's approval of Pfizer/BNT's "COVID-19 Vaccine, mRNA." This product was licensed, or "approved," by the FDA to be made publicly available for injection into humans 16 years of age and older under the proprietary name COMIRNATY.

We learn from the FDA's August 23, 2021, letter regarding the EUA-authorization of "Pfizer-BioNTech COVID-19 Vaccine" that this "vaccine" was first granted EUA by the FDA on December 11, 2020. The FDA reissued the EUA an additional five times prior to August 23, 2021. The last EUA prior to that date was on August 12, 2021. (EUA or approval letters from the FDA to Pfizer/BNT after August 23, 2021, typically pertain to "boosters.")

On August 23, 2021, the FDA concluded that revisions to the August 12, 2021, EUA were "appropriate to protect the public health or safety." Tellingly, the revisions and the reissuance of the EUA coincided with the FDA's approval of COMIRNATY, also on August 23, 2021. In the EUA letter, the FDA reissued:

"The August 12, 2021, letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved ***BLA*** *[emphasis added]."*

"BLA" means "Biologics License Application."

The "approved BLA" is an express reference to the FDA's approval of COMIRNATY in the August 23, 2021, letter to both BioNTech and Pfizer.

What the FDA is saying is that pursuant to the EUA of the "Pfizer-BioNTech COVID-19 Vaccine," which does not have FDA approval, Pfizer is authorized to administer COMIRNATY for uses and purposes for which the FDA did not approve the use of COMIRNATY. One could reasonably ask: Is there any difference between these two products to warrant FDA approval of COMIRNATY?

What's The Difference? It's The Law, Not Science and Medicine.
The FDA itself answers this question in the letter addressed only to Pfizer regarding the EUA-authorization of "Pfizer-BioNTech COVID-19 Vaccine." In that letter, the FDA makes clear that there is no scientific difference between the EUA-authorized "vaccine" and the approved COMIRNATY "vaccine." Rather, any difference is a matter of law, not science. This is what lawyers call a legal fiction.

From that letter we learn that:

"*Pfizer-BioNTech COVID-19 Vaccine [the EUA product] contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. COMIRNATY (COVID-19 Vaccine mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and [COMIRNATY] can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series."*

This quote ends with reference to footnote 8, which reads:

"The licensed vaccine [COMIRNATY] has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness." ((https://www.armstrongeconomics.com/wp-content/uploads/2021/08/FDA-Letter-Final_Pfizer-LOA-to-issue-with-BLA-approval-08.23.21_v2.pdf, p. 2.)

There you have it. The FDA EUA-authorized product and the FDA-approved COMINARTY are scientifically identical and can be used, medically speaking, interchangeably; but they are "legally distinct." This legal distinction is based upon an alleged, and fraudulent, ongoing health emergency and the statutory law, rules and regulations applicable to the FDA when such an emergency – real,

imagined or trumped-up – is declared to exist by the people and agencies in which the public is expected to dutifully repose trust and confidence.

Unconscionably, these so-called laws have been applied by the FDA to authorize use of COMIRNATY for children aged 12-15, when COMIRNATY has not been licensed/approved for that age group. Given that there is admittedly no scientific and medical difference between these two products, there is no rationale and defensible justification for the FDA to authorize the use of COMIRNATY when it has not approved the use of COMIRNATY for children aged 12-15.

Why Have Concerns About Safety and Effectiveness for Children? The FDA Is Not Concerned. Or Is It?

In the FDA's August 23, 2021, letter to Pfizer/BNT granting a license/approval for COMIRNATY in the USA, the FDA approved the manufacture of COMIRNATY to be administered to humans 16 years of age and older. (The FDA set a number of conditions to this approval which have yet to be met and will take years to do so, if at all.) However, Pfizer/BNT's BLA (Biologics License Application) also sought a license to administer COMIRNATY to 12–15-year-old children, as well as to humans 16 years of age and older. Notably, the FDA advised Pfizer/BTN that it had concerns about the pediatric use of COMIRNATY in children ages 12-15 because Pfizer had not fulfilled the pediatric study requirements for this age group. In part, for that reason, as well as others, the FDA did not license/approve COMIRNATY for the 12-15 age group. Instead, it required Pfizer/BNT to conduct a number of studies and set timetables to do so. Many of the dates in the timetables do not expire until 2025, 2026 or 2027. Meanwhile, employing an expedient legal fiction, the FDA has authorized the use of the EUA product on children aged 12-15 when it does not (and should not) approve the use of COMIRNATY for this age-group (or for any age group).

Unsurprisingly, the FDA did find that Pfizer/BTN had fulfilled the pediatric study requirements for the 16-17 age group. How much weight, if any, should the public put on the FDA's finding? Interestingly, regarding the 16 and older age group, the FDA stated:

"We did not refer your application to the Vaccines and Related Biological Products Advisory Commission because our review of the information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefitted from an advisory committee discussion." (https://www.fda.gov/media/151710/download), p. 2.)

No concerns. Oh, really? The clinical study design and trial results, as well as the safety, efficacy and medical necessity of the Pfizer products (not to mention the other "vaccines" for "COVID-19 disease"), have been reasonably and effectively challenged by many qualified medical and other experts, many of whom also question the FDA's decision to bypass the Vaccines and Related Biological Products Advisory Commission. It is reasonable to conclude that the FDA and Pfizer did

not want such a review, as it would have shed light on and called into question the FDA's conclusion that these products are safe, effective and medically necessary.

On a related note, after the FDA issued the August 23, 2021, letters many media outlets falsely claimed that the FDA had licensed and approved both Pfizer mRNA products. To that end, these media sources intentionally and recklessly gave the impression to the public that everyone who received the Pfizer injection would be administered only the "approved" COMIRNATY. That was not, and is not, true. Consequently, in the opinion of this writer, any discussions about whether COMIRNATY is available and being administered in the United States are rendered moot and non-productive. What difference does it make when the only distinction between the two is artificial and expedient? The distinction is to be found only in the law and not the science. Indeed, to again quote the FDA, "the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns."

While the FDA expressed no concerns about administering COMIRNATY to humans 16 years of age and older, it expressed concerns about administering COMIRNATY to children aged 12-15. Yet, incredibly, inconsistently and dangerously, despite the EUA-authorized product and COMIRNATY being scientifically identical and interchangeable, the concerns the FDA had about administering COMIRNATY to children aged 12-15 were intentionally and reprehensively tossed to the wayside when the FDA gave EUA-authorization to Pfizer to administer COMIRNATY to children age 12-15 under the pretext of an alleged health emergency. There's that legal distinction, actually legal fiction, at work in real-life, with its severe and irreparable injurious and deadly consequences.

The so-called legal distinction, but without any scientific/medical difference, between the EUA-authorized product on the one hand, and the licensed/approved COMIRNATY on the other hand, must come as little or no consolation to parents whose children received COMIRNATY and to those who have been administered COMIRNATY and/or the EUA-authorized product and are suffering, or will suffer, adverse events as a direct result — regardless of their age.

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Report 13: "Adverse Events Rise in Babies Breastfed by Vaccinated Mothers" – Team 3.

Is COVID-19 vaccination safe for pregnancy and breastfeeding?

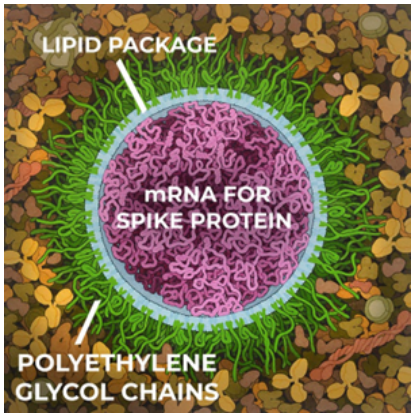
BREASTFEEDING AND COVID VACCINATION

In pregnancy and breastfeeding, any substance is guilty until proven innocent. The COVID-19 vaccines are declared safe for pregnancy and breastfeeding by authorities in their field, such as the ABM (Academy of Breastfeeding Medicine., 2021)**. Is this recommendation based on science or fantasy? Is the COVID-19 vaccine safe for pregnancy and breastfeeding? I do not know the answers to these questions. We look to "The Science" to find out. And we find that the authorities in medicine and medical sciences don't know the answers because no one has done the evaluation. But those who adhere to the known science have a strong foundation to question safety because "Before a product is declared safe for breastfeeding or pregnancy, the answer be known". The great tragedy of thalidomide in the 1950s and disaster of widespread smallpox vaccination during an epidemic in the late 1870s taught us the bitter lesson.**

Our journey to understand the safety or lack of safety will be based on the strict science. We will begin with what is known. If some cases, we will need to bring in some foundational information. If a recommendation by an authority is based on opinion and not science, this will be pointed out. If the recommendation goes contrary to the known science, that will be pointed out.
Before we start, we need to emphasize that there are 3 vaccines on the market in the US. Two of them are mRNA vaccines (made by Pfizer/BioNTech and Moderna, respectively) and one is adenovirus vaccine (made by JNJ but now pulled from the market).

When we talk about a COVID-19 vaccine being safe for breastfeeding or pregnancy, it is not clear that one size fits all and we should not lump all COVID-19 vaccines together. Nor can we look at pregnancy and breastfeeding as a single entity and assume if one is safe or harmful for one it is the same for the other. That said, we will lump the mRNA vaccines together to an extent as they are similarly constructed and look at the adverse effects from their individual components and if the adverse reaction is due to the spike protein.

The mRNA vaccine is a composite product consisting of an mRNA core wrapped in a lipid blanket Lipid is the scientific term for fat.



The core of the vaccine is the mRNA which will code for the spike protein. The core is surrounded by 3 layers of lipid to facilitate entry into cells. The first layer is the lipid nanoparticle. The second layer is PEG. PEG is polyethylene glycol. PEG is similar to antifreeze and there are many different types of PEGs. The vaccines use ALC 0159. A third lipid is added called an emulsifier along with cholesterol. The vaccine is unstable at room temperature requiring it to be kept at very cold temperatures. Wrapping the mRNA core in these lipid layers allows it to merge with cells. The lipid nanoparticle penetrates the blood brain barrier (Christensen, 2014), the placental barrier (Huang et al., 2015), (Wick, 2010), fatty breast tissue (Golan Y. e., 2021) and breast milk. The lipid nanoparticle, even without the mRNA component, is highly inflammatory. (Ndeupin, 2021). The mRNA vaccine induces a potent immunological response in the breast and in the breast milk. (Narayanaswamy et al., 2022)

Before we delve into the adverse reactions and the actual science as to why these occur, it behooves us to examine the misleading advice given by prominent medical societies.

> The Academy of Breastfeeding Medicine. ABA M Statement tells us that the vaccine is made of lipid nanoparticles that contain mRNA (which will code) for the SARS-CoV-2 spike protein (once it is in the cells). (P*arenthesis added for clarification*). These particles are injected into muscle. Here the nanoparticles are taken up by muscle cells. These muscle cells then transcribe the mRNA to produce spike protein. The spike protein made by the cell stimulates an immune response. (Academy of Breast Feeding Medicine., 2021). *Note: All of these statements are true but are not relevant as to the safety of the vaccine for breastfeeding.*
>
> According to the ABM, during lactation it is unlikely that the vaccine lipid would enter the bloodstream and reach breast tissue. (*Note: This is speculation unsupported by experimental evidence. It is irresponsible for an authority figure to make such a speculation in the absence of evidence. Additional evidence showed this statement to be false)*. If it does, it is even less likely that either the intact nanoparticle or mRNA transfer into milk. (*Note: This speculation proved to be false*). In the unlikely event that mRNA is present in milk, it would

> be expected to be digested by the child and would be unlikely to have any biological effects. (*Note: This is speculation and given the asymmetrical risk of being wrong, it is not worthy of any who has had training in medicine, whose first oath is to do no harm. It is a question of the utmost importance. Preliminary evidence indicates that this is a false statement, and the immunological effects are profound (Narayanaswamy et al., 2022)*).

Compare the above statements to the actual experimental evidence. In every case the speculation is proved wrong by experimental evidence. Experimental evidence is the foundation of the science that we are to follow.

> While there is little plausible risk for the breast-fed infant (*Note: the lack of plausible risk is speculation*), there is a biologically plausible benefit. Antibodies and T-cells stimulated by the vaccine may passively transfer into milk. (*Note: This is a true statement*). Following vaccination against other viruses, IgA antibodies are detectable in milk within 5 to 7 days. (*Note: This is a true statement but there is speculation that antibodies produced by vaccination are equivalent to IgA antibodies of natural infection. It is assumed that passive transfer of activated T cells is a good thing. This is spectacularly wrong).* Antibodies transferred into milk may therefore protect the infant from infection with SARS-CoV-2. Although the biology is reassuring, for definitive information, we will have to wait for data on outcomes once the vaccine is used in lactating individuals and their children. (*Note: this is the only valid statement*).

It is essential to note that the ABM assumes, without evidence, that the vaccine and transfer of antibodies and other inflammatory cytokines are beneficial to the breastfeeding infant and fails to consider the question as to whether they are harmful. They are only concerned with the ability to protect from SARS COV-2. This tunnel vision is reprehensible as SARS COV-2 offers little harm to the infant, but initiation of an inflammatory response may prove fatal as explained below.

The ABM does not stand alone. The American College of Obstetrics and Gynecology and The Society for Maternal Fetal Medicine have recommended that these mRNA vaccines be made available for lactating women, despite acknowledging that initial trials excluded breastfeeding women and no assessment could be made concerning their safety. (Bertand, 2021-04-25). The World Health Organization recommends that breastfeeding individuals be vaccinated and does not advise cessation of breastfeeding following vaccine administration. (Golan Y. e., 2021). The Academy of Breastfeeding Medicine states that there is little plausible risk that vaccine nanoparticles or mRNA would enter breast tissue or be transferred to milk. (Golan Y. e., 2021). The ABM notes that if the mRNA vaccine entered the breast milk there is a theoretical possibility of priming the infant immune system. (Golan Y. e., 2021).

Let's compare this to the actual science: the mRNA does enter the breast, does initiate an immune response (Narayanaswamy et al., 2022) **and is highly inflammatory.** (Ndeupin, 2021) As the original trials did not look at breastfeeding, two studies at breastfeeding were done. One evaluated breast-fed children for a 4 to 48 hr. period following vaccination. (Golan Y. e., 2021). The second found approximately 10% of breast-fed children had adverse events, the events were worse after the second dose and with Moderna but concluded that the adverse events were not serious (Bertand, 2021-04-25). Little comfort can be drawn from these studies as the studies are small, underpowered, non-randomized and not blinded. One of the studies used self-reporting. We have been lectured ad nauseum by Dr. Anthony Fauci that only randomized, controlled, double blind studies count**. Underpowered studies mean that is not enough data to draw valid conclusions. Not only is the conclusion not valid, but it is also often opposite of the true effect.**

Any study that examines the safety of breastfeeding following vaccination needs to evaluate the recipient infant. The breastfeeding infant is taking the breast milk by mouth and so the GI tract is the target organ. This means that studies looking at adverse vaccination events from intramuscular injections cannot be used. A better model is from natural infection. In natural infection, the virus infects the upper respiratory tract and then is swallowed into the GI tract where it initiates a systemic, IgG based immunological response. A newborn infant and up to about 6 months has an immature immune system. The key question is how the immature immune system of the breastfeeding infant reacts to the inflammatory cytokines and chemokines found in breast milk. **We don't know the answer as it was not evaluated. But we do know this.** The breast immune response produces potent chemicals called chemokines and cytokines that have profound immunological effects. One that is of particular concern is interferon gamma and the very high levels of interferon gamma that are produced. (Narayanaswamy et al., 2022) These are transferred to the infant in breast milk. High dose interferon gamma is a liver toxin. The other cytokines may change the infant's immune response from Th2 mediated, that leads to antibody protection, to Th1 response that increases interferon gamma even more.

The mRNA vaccine induces the mother's cells to produce spike protein. This protein is cleaved with the S1 subunit discarded into the circulation. This S1 component of the vaccine lasts for weeks and produces far higher S1 protein subunits than natural infection. (Röltgen et al., 2022) This means that during each breastfeeding, the amount of spike protein and S1 sub-unit protein is building in the infant's gastrointestinal tract. Even if the first exposure is miniscule, continued feeding increases the dose. The level of spike and S1 protein likely builds over time in the infants GI tract and may find entrance into circulation.

The lipid nanoparticle, without the mRNA payload, is highly inflammatory by itself. (Ndeupin, 2021). The lipid nanoparticle can cross the placenta and induce trophoblast to undergo apoptosis (programmed cellular death of a damaged cell). (Huang et al., 2015)

The other component of the mRNA vaccine is PEG. Assessment of likelihood of adverse reaction needs to evaluate whether PEG or PEG antibodies are transferred from mother to the infant and results in sensitization and potential of initiating a severe allergic adverse reaction.

PEG ALLERGY and the COVID VACCINE

One of the major components of the mRNA vaccine is PEG. PEG is polyethylene glycol. It comes in many variants and each variant has its own chemical properties. The PEG used for mRNA vaccine is known by the chemical identifier ALC 0159. It is used in many medications, cosmetics, and food products. The widespread use of PEG has sensitized many in the population to PEG and this sensitization is often unknown or unsuspected. (Hypersensitivity to Polyethylene Glycols & Polysorbates - Physician's Weekly, n.d.)

The seriousness of the allergic response is not only dependent on the dose of the PEG but also whether the immune system is primed to react towards PEG. The amount of PEG in a vaccine is qualitatively minute, bordering on undetectable (Golan Y. e., 2021) but the amount of PEG present can induce anaphylaxis or a serious allergic response. ((Golan Y. e., 2021). (Sellaturay, 2021) , (Hypersensitivity to Polyethylene Glycols & Polysorbates - Physician's Weekly, n.d.) Many normal individuals also have pre-existing antibodies against PEG in their circulation and are primed to react against PEG. (Chen, 2021). When a mother is immunized her breast milk carries many cytokines and chemokines. (Narayanaswamy et al., 2022) These chemokines and cytokines are the same chemicals that are released in an anaphylactic reaction to PEG. (Janeway, 2001)

The gut reaction to PEG is different from the intradermal or skin reaction. The amount of PEG in breast milk is negligible (Golan Y. e., 2021) and below detection ((Golan et al., 2021)) but still present. If the mother has been sensitized and passes on this sensitization in her breast milk to the infant, even if she is not showing signs of sensitization, then the immature immune system of the infant may be triggered and undergo a reaction even to a minute amount of PEG.

In a separate issue, the breastfeeding infant may initiate an immune response independent of PEG. This is dependent on the amount of interferon gamma that the mother is passing to the breastfeeding infant. The mother is also passing the S1 subunit of the spike protein. The S1 subunit is produced in abundance by the vaccinated mother, and it is likely that this excess is distributed into the breast milk. In the presence of excessive interferon and S1 subfraction, a non-specific hyperactivation of the cell immune response results. (University of Pittsburgh, 2022). (Brodin, 2022)

We are back at our beginning question: Is it safe to vaccinate a breastfeeding mother? The science raises many questions that preclude a blanket statement of safety. Wisdom paid for by the unmeasurable disasters of the past answers decisively: No, as the risk to the infant from COVID-19 is virtually zero, but the potential risk of adverse reactions from the vaccine are real and measurable.

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Report 14: "MicroRNA, the Hidden RNA in the Pfizer mRNA Vaccine" by Daniel B. Demers, PhD – Team 5.

Introduction

MicroRNAs (miRNAs) are a class of non-coding RNAs that play a role in a multitude of cellular processes. The first miRNA was discovered in 1993 in a nematode (O'Brien et al., 2018; Lee et al., 1993). The first viral miRNA was only identified in 2004 (Pfeffer et al., 2004). Thus, the history of miRNAs is short, and therefore, limited scientific data has been gathered on this special class of RNA.

On average mature miRNAs are just 19-22 nucleotides in length (O'Brien et al., 2018; Mallick et al., 2009). By comparison with messenger RNA (mRNA), a coding RNA, the average mature mammalian mRNA is typically 2,200 nucleotides long. The full-length mature SARS-CoV-2 mRNA is about 29,900 nucleotides long while the Pfizer vaccine spike protein mRNA is 4,284 nucleotides long (Nance et al., 2021; Kim et al., 2020).

MicroRNAs are highly stable molecules, contrary to mRNA molecules (O'Brien et al., 2018). The SARS-CoV-2 spike protein mRNA is unstable (Pallesen et al., 2017), which is why Pfizer made modifications to stabilize it and prevent its degradation in the body.

Although miRNAs are small, they are abundant and critical for normal animal development. They function in gene expression, mRNA stability and degradation, regulation of translation (protein production), and wound healing. They can act as chemical messengers to mediate cell-cell communication and can be released into the extracellular fluids and delivered to other cells and organs, thus exhibiting hormone-like activities. It is estimated that 60% of mammalian genes are influenced by miRNAs which affect regulatory pathways including cancer, apoptosis (cell death), metabolism and development. MicroRNAs have been detected in plasma and serum, cerebrospinal fluid, saliva, breast milk, urine, tears and seminal fluid (Marchi et al., 2021; Abedi et al., 2021; Khan et al., 2020; O'Brien et al., 2018).

There is a delicate balance within the miRNA regulatory system. There is an interaction of miRNAs with their target genes, mRNA molecules, other endogenous miRNAs as well as exogenous miRNA and other nucleic acids (viral and bacterial). It is a highly dynamic system that is dependent on many factors including miRNAs' relative abundance. O'Brien et al. (2018) point out that alterations in host miRNA levels would interfere with specific cellular processes crucial for host biology. In fact, evidence indicates that miRNA expression and dysregulation are associated with the development of pathological processes and chronic diseases, including viral infections and the diseases caused by viral infections (Marchi et al., 2021; Zhang et al., 2021; Giardi et al., 2008).

It has been shown that miRNAs play a crucial role in host antiviral responses and viral pathogenesis of various viruses. MicroRNAs can modulate innate and adaptive immunity by affecting protein levels. Viral genomes can express their own miRNAs and can "hijack human miRNAs to the repertoire of the infected cells" (Abedi et al., 2021). MicroRNAs are known to play a role in the pathogenesis of other coronaviruses, such as SARS-CoV and the Middle East Respiratory Syndrome coronavirus (MERS-CoV) that caused epidemic outbreaks in 2003 and 2012, respectively (Mallick et al., 2009; Hasan et al., 2014). The SARS-CoV-2 genome, including the spike protein mRNA, have been shown to encode their own miRNAs, some of which interact with human miRNAs (Liu et al., 2020).

SARS-CoV-2 encoded miRNAs can target different organ-specific cellular functions including insulin signaling and heart development related pathways which might lead to diabetes and consequences similar to viral myocarditis, respectively. These viral encoded miRNAs might also target genes associated with brain development which might provide a clue about neurological signs like headaches, vomiting and nausea (Khan et al., 2020).

Viral miRNAs encoded by the SARS-CoV-2 genome can target several host genes. One study predicted that 3,377 human genes were potential targets of 170 miRNAs produced from the SARS-CoV-2 genome. Also, 10 human miRNAs were identified that possess binding sites across the SARS-CoV-2 genome. Said another way, there are human miRNAs binding to the SARS-CoV-2 mRNA and there are SARS-CoV-2 encoded miRNAs binding within the human genome (Abedi et al., 2021). Using prediction analysis (theoretical), Sacar Demirci et al. (2020) identified 67 human miRNAs with potential targets in the SARS-CoV-2 spike protein region. If human miRNAs are binding to regions within the spike protein mRNA, then what does a spike protein mRNA vaccine do to the delicate balance within the miRNA regulatory system that O'Brien et al. (2018) described?

"Manipulating the level of host miRNAs could have unintended consequences because the physiological functions of the miRNAs might be altered or viral pathology might be enhanced" (Mallick et al., 2009).

It is clear that viruses encode their own miRNAs that can interact with host DNA, mRNA and miRNAs thereby altering the delicate balance of the miRNA regulatory system. Mishra et al. (2021) proposed that the SARS-CoV-2 spike protein itself is able to modify the host exosomal cargo (with two human miRNAs, miR-148a and miR-590) that get transported to distant uninfected tissues and organs to "initiate a catastrophic immune cascade within the central nervous system" (Mishra et al., 2021). In other words, miRNAs encoded within the SARS-CoV-2 spike protein mRNA cause the infected host cells to package human miRNAs, miR-148a and miR-590, into exosomes (vesicles that release cellular molecules into the extracellular fluid) for export out of the cell to the central nervous system where they initiate pathogenesis.

When a vaccinee receives a Pfizer BNT162b2 mRNA vaccine, they not only receive the vaccine's mRNA, he or she also receive an unknown number of miRNAs, hidden within the sequence of the vaccine mRNA. How do the miRNAs introduced by the Pfizer vaccine disrupt the balance of the host miRNA system? What pathogenesis do they cause? What are the long-term toxicity, carcinogenicity and pharmacological concerns? None of this was studied by Pfizer. In fact, there is no mention of miRNAs in the Pfizer document 2.4 NONCLINICAL OVERVIEW (https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf).

Good science demands answers to these important questions, and the answers should have been obtained before injecting hundreds of millions of people globally (billions of doses) with such an experimental substance.

In summary, miRNAs are being recognized as an enormously important component of gene expression and regulation and are associated with many diseases as well as host immunity (Zhang et al., 2021; O'Brien et al., 2018). It has been demonstrated that SARS-CoV-2 encoded miRNAs, including miRNAs from the spike protein region, bind to the host genome and that host miRNAs bind within the SARS-CoV-2 genome. But there is a delicate balance within the host miRNA regulatory system, and it has been shown that these exogenous miRNAs, as well as exogenous mRNA encoding them, alter this delicate balance with potential deleterious consequences (O'Brien et al., 2018). This undeniably important biomolecule was not mentioned by Pfizer.

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Report 15: "Why COVID-19 Vaccine Consent Must Be Informed" by Vicki F. Goldstein, RN, JD – Team 1.

The doctrine of informed consent has been a bedrock of our health care system for over 60 years. And yet, in pursuit of mass vaccination, the federal government, pharmaceutical companies, and medical associations, including the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP), have blocked truthful information regarding Covid-19 vaccines from the public and significantly interfered with the duty of physicians to inform their patients of the serious risks and limited benefits of the vaccine prior to consent. We are in a battle for information.

The American Medical Association recognizes that "medical ethics, common law and statutory law mandate the informed consent process." (https://www.ama-assn.org/delivering-care/ethics/informed-consent) We have the right to exercise autonomy to make our own medical care decisions, including the important right to decline medical treatment. And the physician has a duty to inform, without which there is no consent. Traditionally, we have trusted the medical profession to honestly discuss with us the risks, benefits and alternative options prior to our consent for treatment. Inexplicably, this vital process has been cast aside with Covid-19 vaccines.

Before examining the failures of informed consent in the context of the Covid-19 vaccine, we look briefly at the doctrine as it evolved through the courts, beginning with the opinion written by Justice Benjamin Cardozo. In this seminal case, the court identified the basis for patient consent, holding that "every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages…" *Schloendorff v. Society of N.Y. Hospital*, 105 N.E. 92, 93 (N.Y. 1914)

One of the first courts to recognize a physician's duty to inform the patient of potential risks and alternatives of a procedure prior to consent, reasoned that "the patient, being unlearned in medical sciences, has an abject dependence upon and trust in the physician…" *Cobbs v. Grant,* 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (Cal. 1972)

And in a case relevant to the issue at hand, the court examined a physician's duty to disclose information of an experimental treatment to the patient. In that case, the patient signed a consent for radiation treatment, which traditionally utilized X-rays. However, the physician chose a new type of radiation treatment using powerful radioactive cobalt that was compared to a three-million-volt X-ray machine. The patient, unaware of the dangers of this new experimental treatment, sustained severe burns. The court held that the physician was obligated and failed to inform his patient of the nature of the treatment and possible dangers within his knowledge. And furthermore, such failure to

inform his patient was considered malpractice. *Natanson v. Klein,* 186 Kan.393, 350 P.2d 1093, rehearing denied 187 Kan. 186, 354 P.2d 670 (1960)

Similarly, Pfizer's mRNA Covid-19 vaccine is experimental. It is not a traditional vaccine, such as measles and polio, that the public understands and has experienced through a lifetime of vaccinations.

Rather, it is a new biological agent consisting of (1) mRNA, which is genetic material containing instructions to train cells to make a spike protein, which is the protein found on the outer wall of coronavirus; (2) lipid nanoparticles, which surround the mRNA as it is transported to the cell; and (3) polyethylene glycol (PEG), which protects lipid nanoparticles that deliver the mRNA.
It is "a triad never used in clinical vaccines and is going to be tested on hundreds of millions of people." (https://biomedres.us/pdfs/BJSTR.MS.ID.005501.pdf)

Additionally, Pfizer's COVID-19 vaccine does not provide immunity, a fact that prompted the CDC in 2021 to remove the word "immunity" from the long-standing definition of vaccines.

While Covid-19 vaccines are clearly a departure from traditional vaccines, the devastating facts that further compel informed consent are the unknown risks and the volume of known serious adverse events reported in VAERS, medical journals, and the monthly release of court ordered Pfizer documents. The mRNA vaccine is leaving a trail of injury and death as it sweeps across this country.

Against this backdrop, it is a tragedy that medical associations, the federal government, pharmaceutical companies, and the media are holding hostage the truthful information that is required for informed consent. For the safety of the public, informed consent is imperative.

Turning to the unethical conduct of medical associations, DailyClout and a Team 1 physician recently exposed ACOG for persistently advocating for pregnant women to get the experimental Pfizer Covid-19 vaccine. They did this with full knowledge that pregnant women were not explicitly approved or authorized during pregnancy and lactation. According to the report, ACOG relied on a faulty rat study (DART), which was incomplete and biased, in order to determine that the vaccine was safe for pregnant women. In fact, the Pfizer Covid-19 vaccine is not safe, as evidenced by the volume of data included in the report that indicates multiple serious adverse events to mother and baby.

Not only did ACOG promote the experimental vaccine for pregnant women, but it also provided guidance to its 58,000 physician members that informed consent was not required prior to vaccination. The ACOG clinical practice advisory, published December 13, 2020, stated that "a conversation between the (pregnant) patient and their clinical team may assist with decisions

regarding the use of the vaccines approved under EUA for the prevention of Covid-19…including…the potential efficacy of the vaccine…. (and) the safety of the vaccine for the pregnant patient and the fetus. *While a conversation with a clinician may be helpful, it should not be required prior to vaccination as this may cause unnecessary barriers to access.*" (https://web.archive.org/web/20210218030246/http://e-lactancia.org/media/papers/Vaccinating_Pregnant_and_Lactating_Patients_Against_COVID-19__ACOG20201213.pdf)

ACOG's disturbing message to the medical community is that vaccination is paramount, even if it requires the erosion of patient rights to make informed medical care decisions. ACOG's message is contrary to the prevailing law and medical code of ethics.

A clinician has a duty to discuss with a pregnant patient the information vital to make an informed decision prior to vaccination. The list of vital information is long and growing. It includes the following: (1) the mRNA Covid-19 vaccine is experimental; (2) it is not licensed by the FDA but rather is authorized for emergency use; (3) there is no authorization for emergency use for pregnant women; (4) pregnant women were excluded from clinical trials; (5) the vaccine does not provide immunity or stop transmission of the virus; (6) the vaccine lacks durability; (7) the vaccine does not stay at the injection site but instead travels through the bloodstream; and (8) the vaccine has serious unknown and known safety risks to the mother and baby, including fetal death and congenital abnormalities.

This is not an exhaustive list of vital information important to a pregnant patient prior to vaccination. Dr. Russell Blaylock, a retired neurosurgeon, warned that "immune stimulation during the third trimester dramatically increases the risk of the child becoming autistic or developing schizophrenia later in life….We will not know if women vaccinated during their third trimester will have children with a higher risk of becoming autistic for at least 6 years, the usual time span for symptom appearance." He also noted that it will take until a child reaches adolescence before schizophrenic symptoms can be observed. Dr. Blaylock opines that women need to be warned of this real danger prior to vaccination. (Blaylock RL. COVID UPDATE: What is the truth? Surg Neurol Int 2022;13:167)

Given all the concerning safety data, it is reasonable to conclude that pregnant women referenced in the Daily Clout report, had they been informed and had a choice, would have exercised their right and declined the vaccine, a decision that would have protected their fetuses.

Unfortunately, the trampling of informed consent is not just limited to ACOG. The Assistant Secretary for Planning and Evaluation (ASPE), an office of HHS, is tasked with improving population acceptance of Covid-19 vaccination. In pursuit of that goal, ASPE identified attitudes, such as vaccine hesitancy, individual beliefs, lack of trust in vaccines, and low perceived severity of

the disease as "*barriers that can interfere with vaccine uptake*." "The solution for these barriers is to have health care providers use the right words…" [Gonzales, A.B. et al, Overview of Barriers and Facilitators in Covid-19 Vaccine Outreach (Research Report No. HP- 2021-19) Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, August 2021.]

Mayo Clinic, cited by ASPE, found that clinicians have consistently obtained higher vaccination rates. "Strong recommendations from trusted clinicians may improve vaccine confidence, reduce concerns about safety and *improve uptake of the COVID-19 vaccine."*

So, this trusted clinician is directed to say to the patient: "Covid-19 vaccination is safe and effective, and I strongly recommend that you get your Covid-19 vaccine today." And to address patient concerns, the clinician is advised to explain that "your concern about vaccine safety…is a common misperception that has been sensationalized in popular media." (https://reader.elsevier.com/reader/sd/pii/S0025619620314877?token=A515C8C125EEB578BE5665F3B49A5F56BDE90E1681461E524E710BAD26899E84A9810BE7DF7895CCD711B79589D3B0E2&originRegion=us-east-1&originCreation=20220502123532)

Is there a clinician we can trust to provide honest information about the mRNA Covid-19 vaccine? Pediatricians have long been trusted guardians of the health and safety of children. However, based on a letter and subsequent actions exposing the Covid-19 vaccine position of the American Academy of Pediatrics, parents need to seriously question the information they receive from their pediatricians.

On February 25, 2021, Dr. Lee Beers, President of the AAP, wrote a letter to Dr. Fauci, the FDA, DHHS and the White House, urgently requesting that adolescents and younger children be enrolled in the clinical trial as soon as possible. Even though Dr. Beers acknowledged that *"studies have shown that children under the age of 10 may be less likely to become infected and less likely to spread the virus to others," she reasoned that "children of all ages need to be vaccinated in order for the United States to achieve herd immunity against Covid-19."* (https://web.archive.org/web/20210329214059/https://downloads.aap.org/DOFA/AAP%20Letter%20Urging%20Inclusion%20of%20Children%20in%20COVID-19%20Trials_02_25_21.pdf)

It is shocking to learn that the AAP has been aggressively pursuing the experimental vaccine, not for the benefit of the child, but for herd immunity that cannot actually be achieved through vaccinations.

Echoing the AAP position, a Pfizer supported publication, the Vaccine Education and Equity Project, stated that "*most children who become infected with Covid-19 virus have only a mild illness but vaccinating kids against covid 19 also plays a role in protecting the health of the broader*

community." (https://web.archive.org/web/20210713183805/https://covidvaccineproject.org/wp-content/uploads/2021/06/WhatToKnowAfterReceivingCovid_Adolescents_R2.pdf)

On herd immunity for Covid-19, a group of Israeli physicians wrote that "the increasingly prevalent opinion within the scientific community is that the vaccine cannot lead to herd immunity, therefore there is currently no 'altruistic' justification for vaccinating children to protect at-risk populations." (https://www.israelnationalnews.com/news/304124)

With virtually no benefit, children face known and unknown risks of serious injury or death from Pfizer's Covid-19 vaccine. Sadly, it is the child who must bear the risk of a significant vaccine injury or death and it is the parents who must bear the cost of those injuries.

And those vaccine injuries are real. In April 2021, Israel reported 62 cases of *myocarditis*, mostly in male adolescents and young men days after receiving the Pfizer vaccine, resulting in two deaths. Israel shared these findings with Pfizer. (https://web.archive.org/web/20210808081436/https://americasfrontlinedoctors.org/wp-content/uploads/2021/06/60a600a8de9ddedc233dbb06_4120Toi20Staff20202120Israel20said20probing20link20between20Pfizer20shot20and20heart20problem.pdf)

Since the early report from Israel, VAERS has received hundreds of reports of pericarditis, chest pain, myocarditis and elevated Troponin, all indicating cardiac issues, in adolescents and young adults post Pfizer vaccination.

Between December 2020 and August 2021, there were 1,691 reports submitted to VAERS that met the case definition of myocarditis. 826 cases of myocarditis were among those younger than 30 years of age, and 96% were hospitalized. The actual rate of myocarditis during that interval is likely higher due to underreporting. [Oster ME, Shay DK, Su JR, et al. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021. *JAMA.* 2022;327(4):331–340. doi:10.1001/jama.2021.24110]

In the news media, we have learned of sudden, unexpected deaths of young people, including a 17-year-old Canadian hockey player who complied with a mandate in order to play hockey and died of a heart attack shortly after being vaccinated.

Responding to the Canadian teen's death, Dr. Steven Pelech pointed out that the "chances of dying from COVID is about .003% for people under the age of 24 in Canada" and that for those under 19, the chances of injury from the "vaccine is about four to five times higher than getting infected with SARS-CoV-2 itself." (https://www.lifesitenews.com/news/doctor-blasts-covid-19-vaccination-for-kids-no-such-thing-as-mild-myocarditis/)

And in the United States, physicians with Boston Children's Hospital reported a three month follow-up of 15 adolescents under the age of nineteen, previously admitted to the hospital for acute vaccine-induced myocarditis post Pfizer's Covid-19 vaccination. Cardiac Magnetic Resonance (CMR) imaging showed improvement but unfortunately the majority of the teens also showed persistent late gadolinium enhancement (LGE), which may predict adverse cardiac outcomes, such as sudden cardiac death and overall mortality. The physicians concluded that "follow-up CMR 6-12 months after acute episode should be considered to better understand the *long-term cardiac risks.*" (https://pubmed.ncbi.nlm.nih.gov/35482094/)

The AAP acknowledged that "since April 2021, rare cases of myocarditis and pericarditis have been reported in adolescents and young adults following receipt of mRNA vaccines…." (https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/about-the-covid-19-vaccine-frequently-asked-questions/)

However, the serious safety data for previously healthy children did not deter the AAP. In July 2021, after an abbreviated clinical trial of several thousand children, the AAP recommended that children aged 12 and older get the Pfizer Covid-19 vaccine as soon as possible.

And on October 29, 2021, in a senseless rush to vaccinate everyone, even though the pandemic is apparently over, the FDA issued an EUA for Pfizer's Covid-19 vaccine in children aged five to eleven years old. The Advisory Committee on Immunization Practice (ACIP), a federal committee that includes the AAP and the CDC, recommended approval of the vaccine for young children. The AAP applauded the CDC's Advisory Committee approval of "s*afe, effective Covid-19 vaccine for children Ages 5-11."*

Dr. Beers stated that "sharing this life-saving vaccine with our children is a huge step forward…*Pediatricians are eager to participate in the immunization process and talk with families about this vaccine…"* (https://www.aap.org/en/news-room/news-releases/aap/2021/american-academy-of-pediatrics-applauds-cdc-approval-of-safe-effective-covid-19-vaccine-for-children-ages-5-11/)

It is astonishing that a medical association would declare the vaccine "safe and effective," given all the evidence to the contrary. In light of the AAP's Covid-19 vaccine policy, which guides its 67,000 members, it is unlikely that parents will be afforded an honest discussion with their pediatricians regarding the vaccine's serious safety data, unknown risks, lack of efficacy and minimal benefit for children.

Informed consent is on life support. Truthful information regarding the serious lack of safety, efficacy, and benefit of Pfizer's Covid-19 vaccine for children and pregnant women is an essential

protection for individual patients and a *barrier* to mass vaccination, which is the goal of the pharmaceutical industry, federal government and medical associations.

Ethics and law require that clinicians discuss with their patients information that is vital for them to carefully weigh the risks of the vaccine against the benefits. Armed with information to place on that scale, the risks of serious known and unknown injuries to mother, fetus and child tip heavily against the vaccine, as it is clear there is virtually no vaccine benefit. Failure of clinicians to inform their patients before consent is malpractice. We must demand accountability.

Report 16: "Vaccine 'Shedding': Can This Be Real After All?" by Cindy Weis.

That question, as we have been told, was put to rest over a year ago by the experts who follow the science.

But recently, I have been reading with alarm the reports of hepatitis in young children. Currently, the suspected cause seems to be pointing to an adenovirus infection. Upon reading these reports, my thoughts immediately returned to the vaccines as a possible contributor, the Johnson & Johnson in particular, since it's based on an adenovirus.

I recalled the concerns of forward-thinking medical professionals who during the vaccine development and testing phases warned of a possibility of the vaccines "shedding" in such a way as to be able to transfer from the vaccinated to the unvaccinated.
(https://americasfrontlinedoctors.org/about-us/issue-briefs/identifying-post-vaccination-complications-and-their-causes-an-analysis-of-covid-19-patient-data/)
(Points 3 & 4)

And a more recent observation by Dr. Robert Malone, inventor of the mRNA Vaccine technology: https://www.onenewspage.com/video/20220317/14528668/Dr-Robert-Malone-Can-Vaccinated-People-Infect-Unvaccinated.htm

When these concerns were initially circulated, fact checker sites were full of articles debunking the idea and calling anyone who entertained it a conspiracy theorist. The arguments presented pretty much convinced me that it was impossible for the Johnson & Johnson or mRNA vaccines to spread from one person to another.
(https://www.healthline.com/health/vaccine-shedding and
https://www.usatoday.com/story/news/factcheck/2021/05/07/fact-check-covid-19-vaccinated-people-dont-shed-virus/4971413001/)

At the same time, there were also cautions being voiced that the vaccines had the potential to travel to and collect in various organs of the body, such as the liver. Of particular concern was the damage that could cause to women's reproductive organs.

One article that so eloquently refuted the possibility of shedding the vaccines also argued that it was improbable for components of the mRNA vaccines to migrate from the injection site to other areas of the body since they would degrade within 24-48 hours. Thus, they wouldn't be able to have any negative effects on women's reproductive systems. Their concerns were adamantly debunked by the experts in this Reuters article dated April 23, 2021: https://www.reuters.com/article/factcheck-covid19vaccine-reproductivepro-idUSL1N2MG256.

Well, we are now finding out how heartbreakingly untrue the naysayers' claims about women's reproductive health were. The evidence is mounting that not only are components of the vaccines traveling to and collecting in various organs, but they also appear to be having devastating effects on pregnant women and their babies.

'What I've Seen in the Last 2 Years Is Unprecedented': Physician on COVID Vaccine Side Effects on Pregnant Women (https://link.theepochtimes.com/mkt_app/what-ive-seen-in-the-last-two-years-is-unprecedented-physician-on-covid-vaccine-side-effects-on-pregnant-women_4428291.html)

The agencies involved in regulating the vaccines were aware of these potential negative impacts. They were negligent in having approved them at all, but particularly recommending them for pregnant women.

Flawed CDC Study Wrongly Concludes COVID Vaccines Safe in Pregnancy (https://link.theepochtimes.com/mkt_app/flawed-cdc-study-wrongly-concludes-covid-vaccines-safe-in-pregnancy_4437106.html)

With these inconsistencies in the narrative now coming to light concerning the danger to women from the vaccines, is it unreasonable for one to question some of the other claims made by these same experts?

I have recently been taking a deep dive into the Pfizer documents, researching any references to pregnancy.

According to the Pfizer Clinical Protocol Document, I found that women who are pregnant or breastfeeding were to be excluded from the vaccine trials. They were not allowed to begin them if pregnant:

Page 42
Exclusion Criteria
11. Women who are pregnant or breastfeeding.

And if they became pregnant during the study, they were withdrawn from receiving further vaccinations:

"Stopping Rule Criteria for Each BNT162 Vaccine Candidate:"
Pg 65
8.2.6. Pregnancy Testing
Pregnancy tests may be urine or serum tests, but must have a sensitivity of at least

25 mIU*mL. Pregnancy tests will be performed in WOCBP at the times listed in the SoA, immediately before the administration of each vaccine dose. A negative pregnancy test result will be required prior to the participant's receiving the study intervention. Pregnancy tests may also be repeated if requested by IRBs*ECs or if required by local regulations. In the case of a positive confirmed pregnancy, the participant will be withdrawn from administration of study intervention but may remain in the study.

As I continued my journey through the Protocol document, I found something related to pregnant women that basically scrambled my brain.

It is a description of what constitutes an EDP – an Exposure During Pregnancy.

Pfizer Clinical Protocol Doc: https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf

Amended Document: https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf

Pg 67-69 (Pg 111-113 in Amended document.)
8.3.5. Exposure During Pregnancy or Breastfeeding, and Occupational Exposure
Exposure to the study intervention under study during pregnancy or breastfeeding and occupational exposure are reportable to Pfizer Safety within 24 hours of investigator awareness.

8.3.5.1. Exposure During Pregnancy
An EDP occurs if:
• A female participant is found to be pregnant while receiving or after discontinuing study intervention.
• A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.
• A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:
• A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.
•
• A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception.

While these descriptions of EDP may not specifically involve "shedding" as the means of transfer, there was apparently concern on Pfizer's part that the vaccine could spread between people. So, riddle me this:

1. If there is no way for the vaccine to spread from the vaccinated to the unvaccinated, why would several of these scenarios be considered an exposure to the pregnant women?

2. If it is possible for some part of the vaccine to travel between Pfizer's test subjects and their partners, why is it not possible between say, a vaccinated parent and their unvaccinated child?

In researching this topic, the many fact-check articles "debunking" the idea of vaccine shedding focused their arguments completely on viral shedding, something technically impossible with the current Covid vaccines as none are based on a live virus. However, as noted above, there are alarming signals that the spike proteins introduced by the vaccines are traveling to many areas of the body and causing damage.

Although the following study was done with Covid patients rather than vaccine recipients, I include it to show that spike protein is present in urine with Covid infection. It seems plausible that it could also be present in bodily fluids due to dissemination via the vaccination: https://www.news-medical.net/amp/news/20220406/Study-evaluates-the-presence-of-the-SARS-CoV-2-spike-protein-in-urine-samples-collected-during-the-COVID-19-pandemic.aspx.

Finally, a recent study at the University of Colorado Anschutz Medical Campus School of Medicine has found evidence that vaccinated individuals can pass (shed) vaccine induced antibodies to unvaccinated individuals: https://www.medrxiv.org/content/10.1101/2022.04.28.22274443v1.

In closing, I reiterate the question I began with: Could any of these mechanisms of vaccine related "shedding," or one we have yet to discover be responsible for the mysterious outbreak of hepatitis in our children?

I don't have the answer to these questions and so many others that have been swirling in my mind throughout this pandemic.

These most recent questions are not just swirling, they are screaming to be answered.

The experts have been so wrong on so many levels during the two plus years of Covid insanity. This is yet one more instance where we must keep digging, keep asking questions, keep demanding

answers until all that has been hidden away in dark corners becomes illuminated by the piercing light of truth.

Report 17: "Concerns About Vaccine Candidate Used as Basis for Emergency Use Authorization" – Team 5.

At least one Pfizer study left many safety concerns unanswered, concerns that one would expect to be investigated and resolved before any mRNA vaccine was authorized for emergency use.

Beginning in April 2020, Pfizer, along with study sponsor BioNTech, conducted a Phase 1/2 study to identify preferred vaccine candidates and dose levels (https://clinicaltrials.gov/ct2/show/NCT04368728). One vaccine candidate that Pfizer studied was BNT162b1, which was *not* chosen as the final version of the Pfizer mRNA vaccine, but which was discussed in documents submitted to the Food and Drug Administration (FDA) in support of the Pfizer vaccine emergency use authorization.

One of those documents was a paper based on the Phase 1/2 trial of vaccine candidate BNT162b1 published by Mulligan et al. (2020) in the journal *Nature* (https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf). The paper describes the results of administering BNT162b1 to adults over 18 at three different dosages and at one or two different times (10 or 30 micrograms on days 1 and 21; or 100 micrograms on day 1).

Mulligan et al. argue that in RNA-based vaccines, the RNA is not incorporated into the host genome (p. 3, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf). But this is contrary to findings by other researchers who demonstrate that RNA from the SARS-CoV-2 virus integrates into the host genome (Zhang et al., 2021, https://www.pnas.org/doi/10.1073/pnas.2105968118). It is also contrary to findings that the final version of the Pfizer mRNA vaccine, BNT162b2, is reverse-transcribed into host DNA beginning 6 hours after contact with the vaccine (Alden et al., 2022, https://mdpi-res.com/d_attachment/cimb/cimb-44-00073/article_deploy/cimb-44-00073.pdf). Alden et al. noted that whether the DNA that is reverse transcribed from BNT162b2 is integrated into the cell genome is not known. [Note: mRNA is reverse transcribed into DNA in both studies cited in this paragraph. It is not known whether the DNA resulting incorporates into the host genome.]

The research paper by Mulligan et al. raises additional safety questions. They note that the vaccine candidate they studied (BNT162b1) incorporates N1-methyl-pseudouridine "which dampens innate immune sensing and increases mRNA translation *in vivo*" (p. 3, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf). They report that for the patients who showed changes in their blood after receiving the mRNA vaccine, the largest changes were decreased numbers of lymphocytes (a type of white blood cell that plays a vital role in immune response). In fact, about 50% of the patients receiving their first 30 or 100 microgram dose showed decreased lymphocyte counts. Could the incorporation of N1-methyl-

pseudouridine in the vaccine formulation be related to decreased lymphocyte counts? Could N1-methyl-pseudouridine be related to the unexpectedly long bioavailability of mRNA products?

Changes in blood cell counts were not the only side effects for patients in this study. In a Phase 1/2 study, "patients usually receive the highest dose of treatment that did not cause harmful side effects in the phase 1 part of the clinical trial" (https://www.cancer.gov/publications/dictionaries/cancer-terms/def/phase-1-phase-2-clinical-trial). Mulligan et al. found that as the dosage increased from 10 to 100 micrograms, adverse events such as fever, fatigue, headache, chills, diarrhea, and muscle and joint pain also increased. Reactogenicity was dose-related, as shown by Daily Clout volunteer researchers in Team 5, at a statistically significant level (https://www.dropbox.com/home/Pfizer%20Research/Team%20Reports?preview=Team+5+Report+-++-+Phase+1_2+f.pdf).

These concerns and more arise from the research by Mulligan et al. on a variant of the mRNA vaccine that was ultimately approved by FDA for emergency use. And in spite of these concerns, the researchers state that "the clinical findings for the BNT162b1 RNA-based vaccine candidate are encouraging and strongly support accelerated clinical development . . . for the rapid production of a SARS-CoV-2 vaccine to prevent COVID-19" (p. 5, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf).

Instead of giving a green light to further development, perhaps Pfizer should have thoroughly investigated all safety questions and resolved these concerns before FDA approved any version of the vaccine?

Report 18: "What Did Pfizer Know, and When Did They Know It? Neurological Harms Concealed." – Team 4.

This report assists in answering, "What did Pfizer know, and when did they know it?" concerning its COVID-19 vaccine. The report focuses on neurological complaints post-injection with the Pfizer COVID-19 vaccine, as well as on several other, non-neurological reported symptoms.

The information presented comes from the Centers for Disease Control and Prevention (CDC) Wonder website (CDC.Wonder.gov) through which anyone can access CDC's VAERS system. VAERS is a reporting system for vaccine manufacturers, health care providers, and the general public to notify the CDC of issues, injuries, symptoms, any problem with a vaccine.

The Vaccine Adverse Event Reporting System (VAERS) provides answers to what Pfizer knew about vaccine injuries resulting from its COVID-19 vaccine and when they knew it. The purpose of VAERS is to alert Pfizer, the CDC, and the Food and Drug Administration (FDA) to safety signals requiring investigation.

Below are seven screenshots of six VAERS reports obtained directly from the VAERS system.

1) The first screenshot shows reports of deaths and headaches reported by those vaccinated in January, February, and March of 2021. The mass vaccination of Americans had just started in that time frame. VAERS reports from the first three months gave Pfizer, the CDC and the FDA critical safety signal information to act upon, though they chose not to address the clear safety signals.

This screenshot shows 3,385 deaths reported in three months, as well as 27,084 headaches which will be elaborated upon in another screenshot.
[https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=6227282DDE2B9107FA07D6EF49E0
]

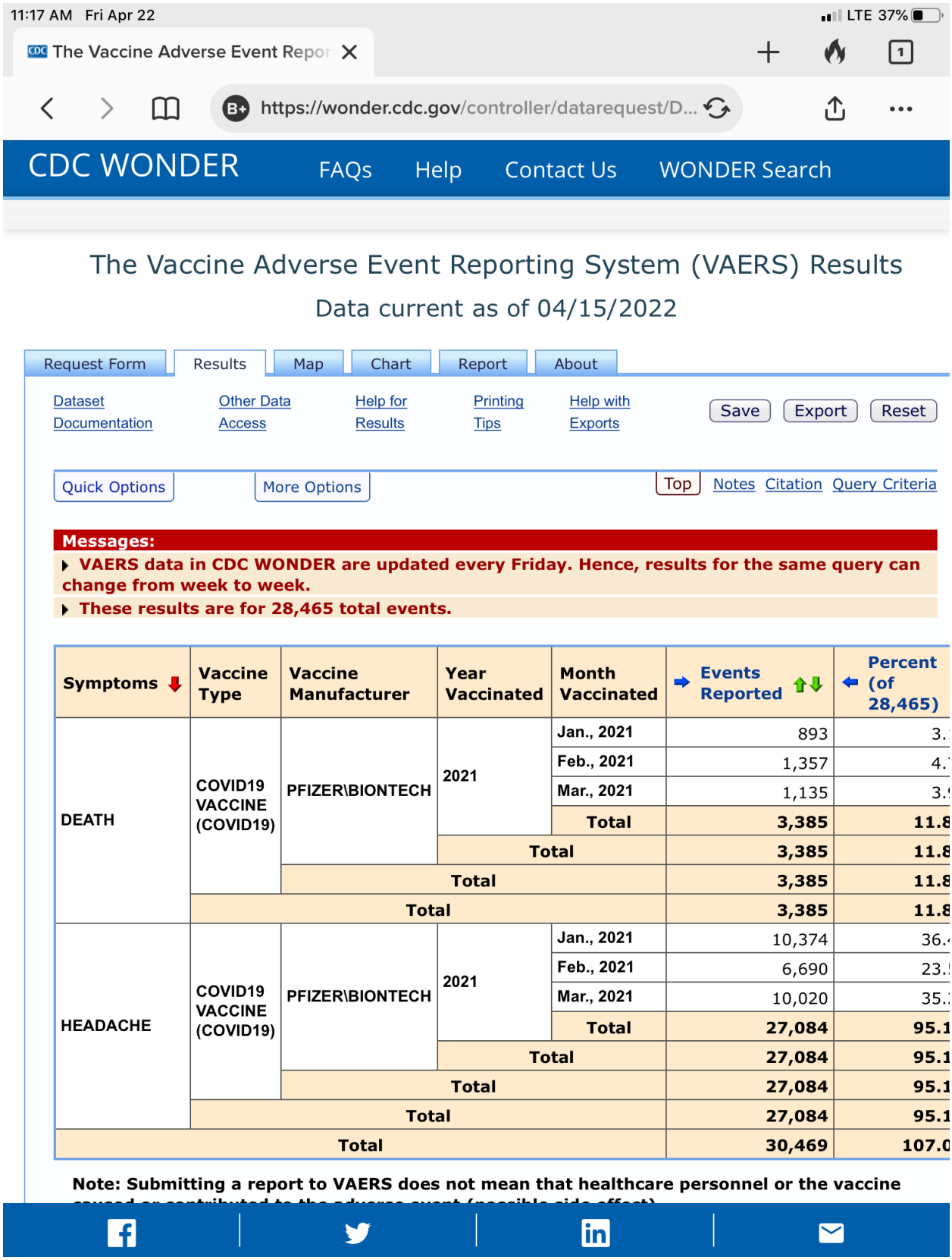
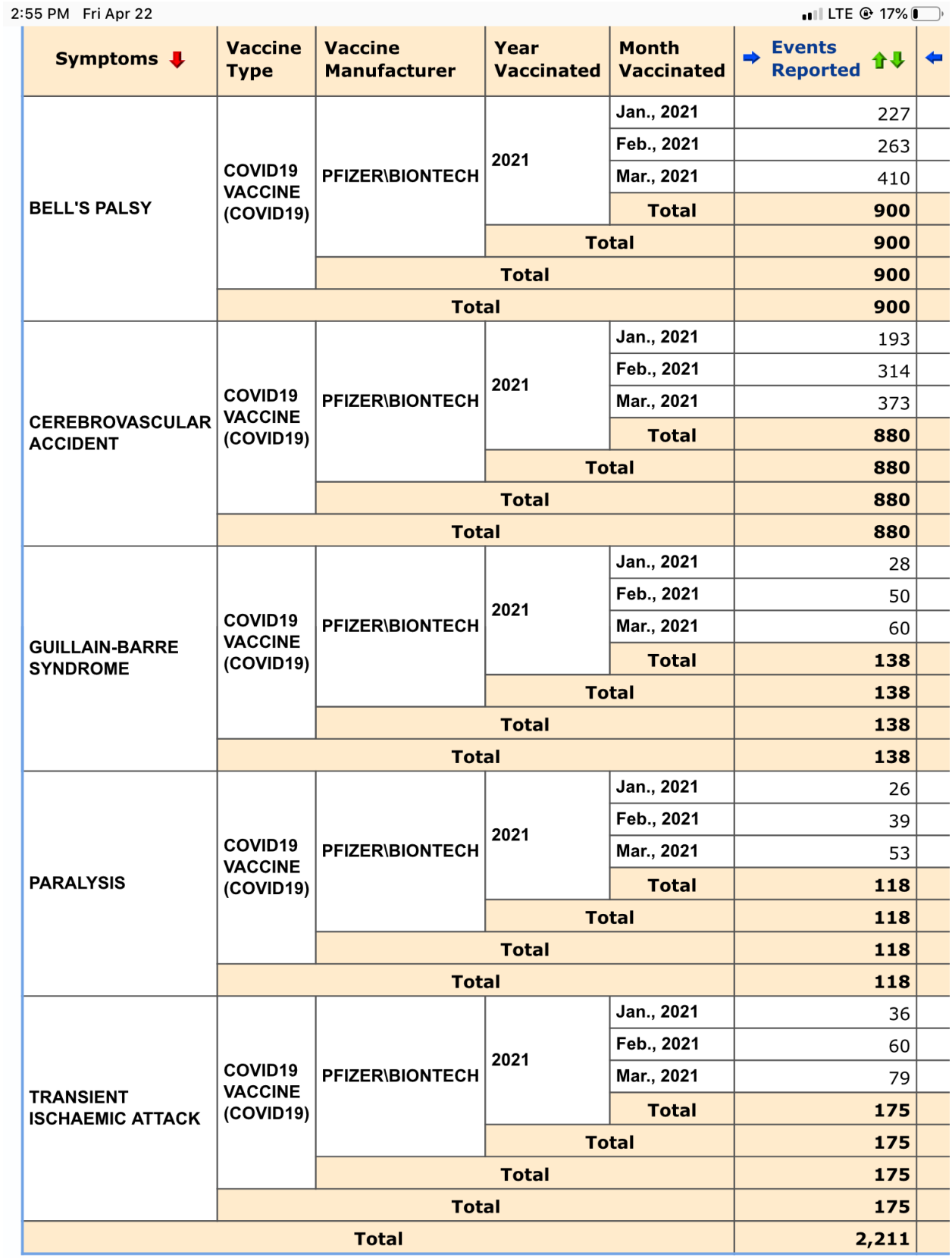


Figure 8: Deaths & headaches from COVID vaccine January through March of 2021 reported in VAERS screenshot

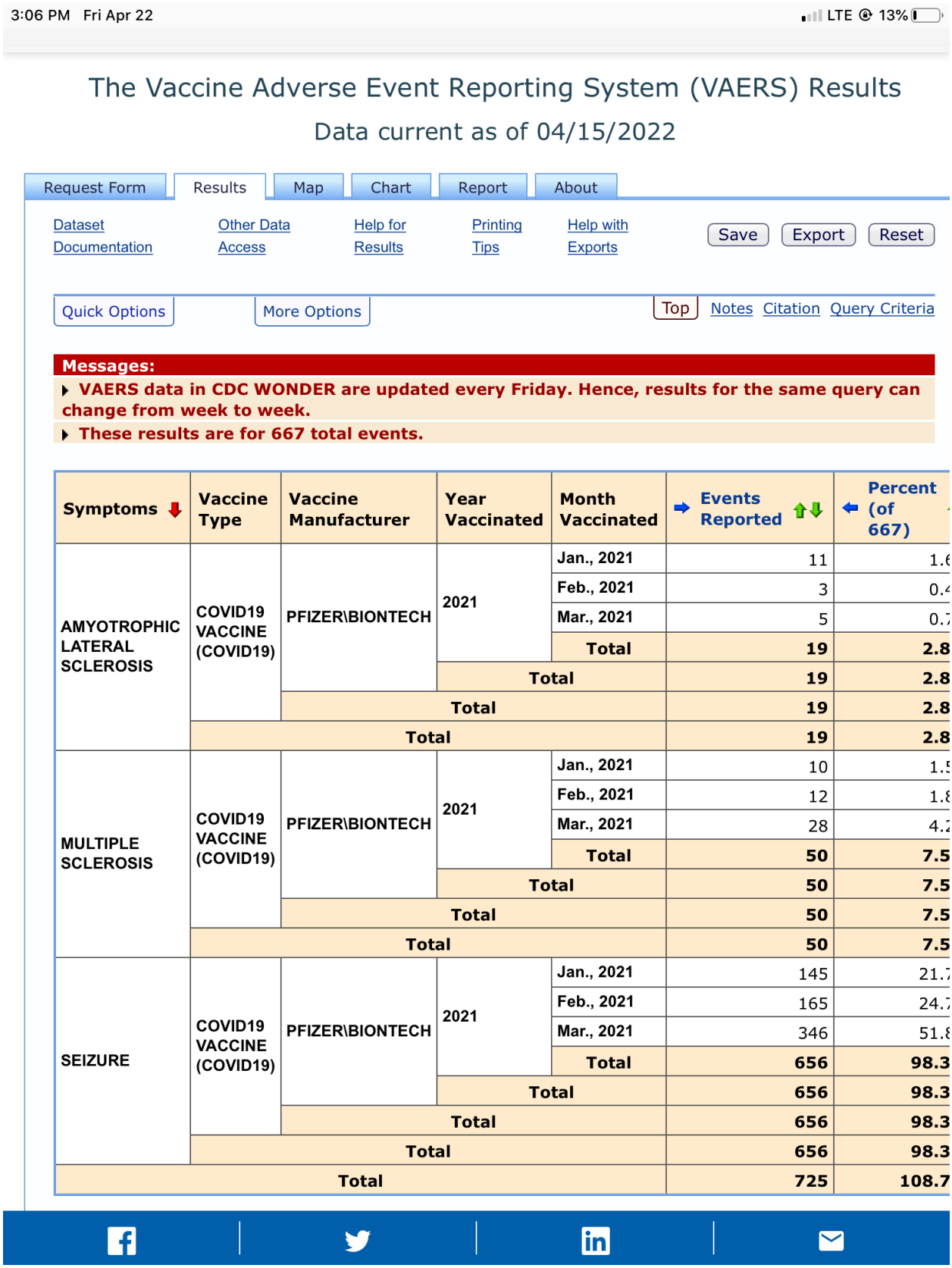
2) The second screenshot presents five categories of serious neurological complaints reported in January, February, and March of 2021: 900 cases of Bell's Palsy; 880 Cerebrovascular Accidents (CVA), also known as stroke; 138 reports of Guillain-Barre Syndrome; 118 reports of paralysis; and 175 of Transient Ischemic Attack (TIA), which is a temporary period of symptoms similar to – but not as severe as – those of a stroke.
[https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=676830642B26323B16BB6DEF1AF6]



Symptoms	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported
BELL'S PALSY	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	227
				Feb., 2021	263
				Mar., 2021	410
				Total	**900**
			Total		**900**
		Total			**900**
	Total				**900**
CEREBROVASCULAR ACCIDENT	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	193
				Feb., 2021	314
				Mar., 2021	373
				Total	**880**
			Total		**880**
		Total			**880**
	Total				**880**
GUILLAIN-BARRE SYNDROME	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	28
				Feb., 2021	50
				Mar., 2021	60
				Total	**138**
			Total		**138**
		Total			**138**
	Total				**138**
PARALYSIS	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	26
				Feb., 2021	39
				Mar., 2021	53
				Total	**118**
			Total		**118**
		Total			**118**
	Total				**118**
TRANSIENT ISCHAEMIC ATTACK	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	36
				Feb., 2021	60
				Mar., 2021	79
				Total	**175**
			Total		**175**
		Total			**175**
	Total				**175**
Total					**2,211**

Figure 9: Bell's palsy, CVA, Guillain Barre,TIA from COVID vaccine January through March of 2021 reported in VAERS screenshot

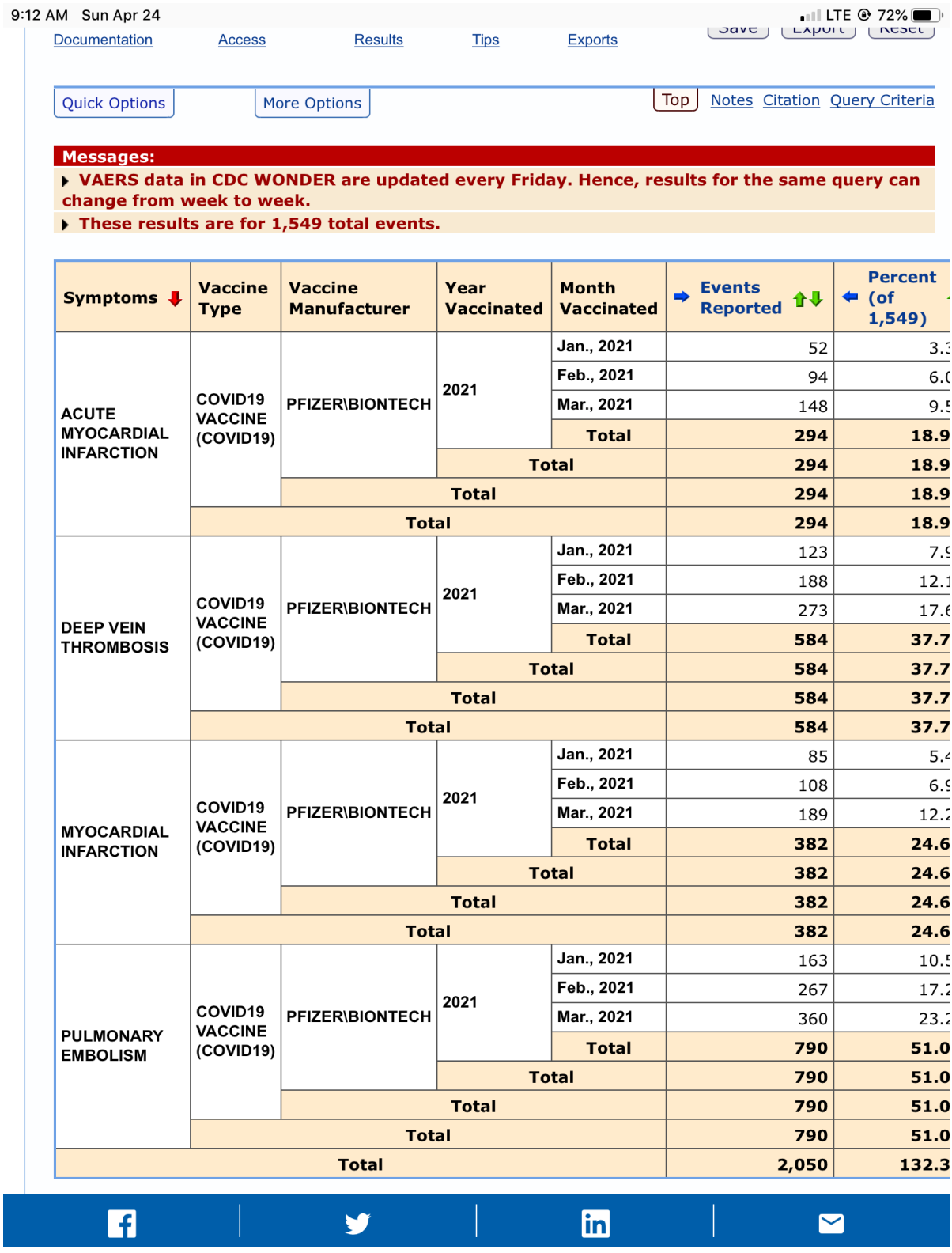
3) Below are the results for three more categories of major neurological symptoms reported in January, February, and March of 2021 — 19 reports of Amyotrophic Lateral Sclerosis (ALS), a progressive nervous system disease that affects nerve cells in the brain and spinal cord, causing loss of muscle control; 50 reports of Multiple Sclerosis; and 656 seizures. [https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=676830642B26323B16BB6DEF1AF6]



Symptoms	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported	Percent (of 667)
AMYOTROPHIC LATERAL SCLEROSIS	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	11	1.6
				Feb., 2021	3	0.4
				Mar., 2021	5	0.7
				Total	**19**	**2.8**
			Total		**19**	**2.8**
		Total			**19**	**2.8**
	Total				**19**	**2.8**
MULTIPLE SCLEROSIS	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	10	1.5
				Feb., 2021	12	1.8
				Mar., 2021	28	4.2
				Total	**50**	**7.5**
			Total		**50**	**7.5**
		Total			**50**	**7.5**
	Total				**50**	**7.5**
SEIZURE	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	145	21.7
				Feb., 2021	165	24.7
				Mar., 2021	346	51.8
				Total	**656**	**98.3**
			Total		**656**	**98.3**
		Total			**656**	**98.3**
	Total				**656**	**98.3**
Total					**725**	**108.7**

Figure 10: ALS, MS, Seizure from COVID vaccine January through March of 2021 reported in VAERS screenshot.

4) While CVA and TIA, shown in the second screenshot above, are neurological complaints, they are caused by blood clots in the brain. Therefore, reviewing several other symptoms also caused by blood clotting issues is pertinent. The screenshot below shows reports of 294 Acute Myocardial Infarction (i.e., acute heart attack), 584 Deep Vein Thrombosis (DVT), and 790 Pulmonary Embolism in January, February, and March of 2021. [https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=51F5E583E6AEF7AE1A6A1BDCFD1B]



Symptoms	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported	Percent (of 1,549)
ACUTE MYOCARDIAL INFARCTION	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	52	3.3
				Feb., 2021	94	6.0
				Mar., 2021	148	9.5
				Total	**294**	**18.9**
			Total		**294**	**18.9**
		Total			**294**	**18.9**
	Total				**294**	**18.9**
DEEP VEIN THROMBOSIS	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	123	7.9
				Feb., 2021	188	12.1
				Mar., 2021	273	17.6
				Total	**584**	**37.7**
			Total		**584**	**37.7**
		Total			**584**	**37.7**
	Total				**584**	**37.7**
MYOCARDIAL INFARCTION	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	85	5.4
				Feb., 2021	108	6.9
				Mar., 2021	189	12.2
				Total	**382**	**24.6**
			Total		**382**	**24.6**
		Total			**382**	**24.6**
	Total				**382**	**24.6**
PULMONARY EMBOLISM	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	163	10.5
				Feb., 2021	267	17.2
				Mar., 2021	360	23.2
				Total	**790**	**51.0**
			Total		**790**	**51.0**
		Total			**790**	**51.0**
	Total				**790**	**51.0**
Total					**2,050**	**132.3**

Figure 11: Acute myocardial infarction, pulmonary embolism, DVT from COVID vaccine January through March of 2021 reported in VAERS screenshot.

5) The following screenshot shows that there were no reports of Acute Myocardial Infarction, death, and Pulmonary Embolism from 2015 through 2019 after receiving *any* Pfizer vaccine, prior to the COVID-19 vaccine debuted. Hundreds of Pfizer vaccines are listed in the VAERS system for 2015-2019. Yet, no one reported incidences of Acute Myocardial Infarction, death, or Pulmonary Embolism after receiving a Pfizer vaccine during those five years. [https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=033107A2EA6A73EEDFA7EDAA68BE]

Data current as of 04/15/2022

Request Form | Results | Map | Chart | Report | About

Dataset Documentation | Other Data Access | Help for Results | Printing Tips | Help with Exports | Save | Export | Reset

Quick Options | More Options | Top | Notes | Citation | Query Criteria

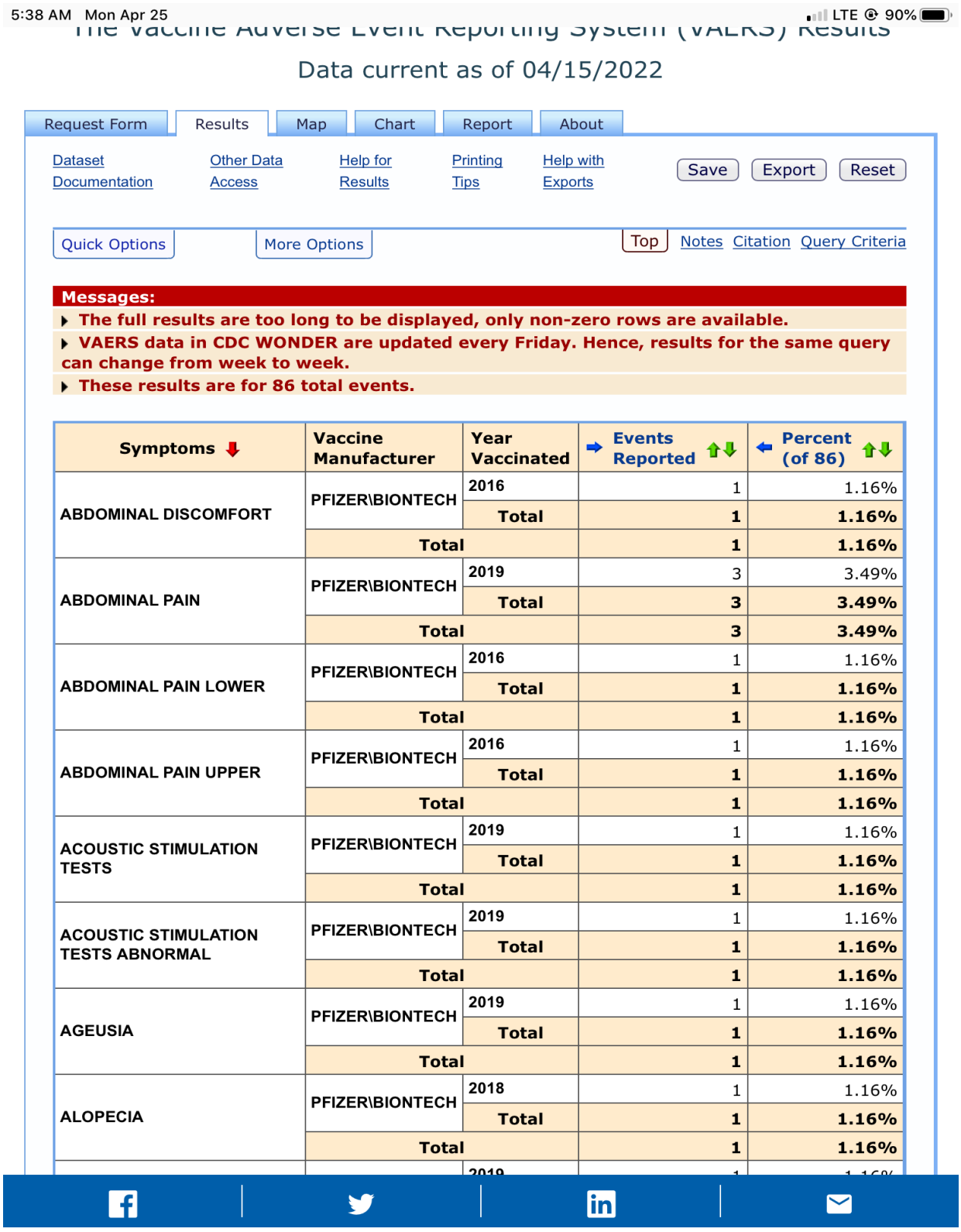
Messages:

- **No non-zero results were found for your query. Use Quick Options above to show zero rows.**
- **You can also check for Caveats in the Notes section; they might contain information about why only non-zero results were returned.**
- **VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.**
- **These results are for 0 total events.**

Symptoms	Vaccine Manufacturer	Year Vaccinated	Events Reported	Percent (of 0)
ACUTE MYOCARDIAL INFARCTION	PFIZER\BIONTECH	2015	0	0.00%
		2016	0	0.00%
		2017	0	0.00%
		2018	0	0.00%
		2019	0	0.00%
		Total	**0**	**0.00%**
	Total		**0**	**0.00%**
DEATH	PFIZER\BIONTECH	2015	0	0.00%
		2016	0	0.00%
		2017	0	0.00%
		2018	0	0.00%
		2019	0	0.00%
		Total	**0**	**0.00%**
	Total		**0**	**0.00%**
PULMONARY EMBOLISM	PFIZER\BIONTECH	2015	0	0.00%
		2016	0	0.00%
		2017	0	0.00%
		2018	0	0.00%
		2019	0	0.00%
		Total	**0**	**0.00%**
	Total		**0**	**0.00%**
Total			**0**	**0.00%**

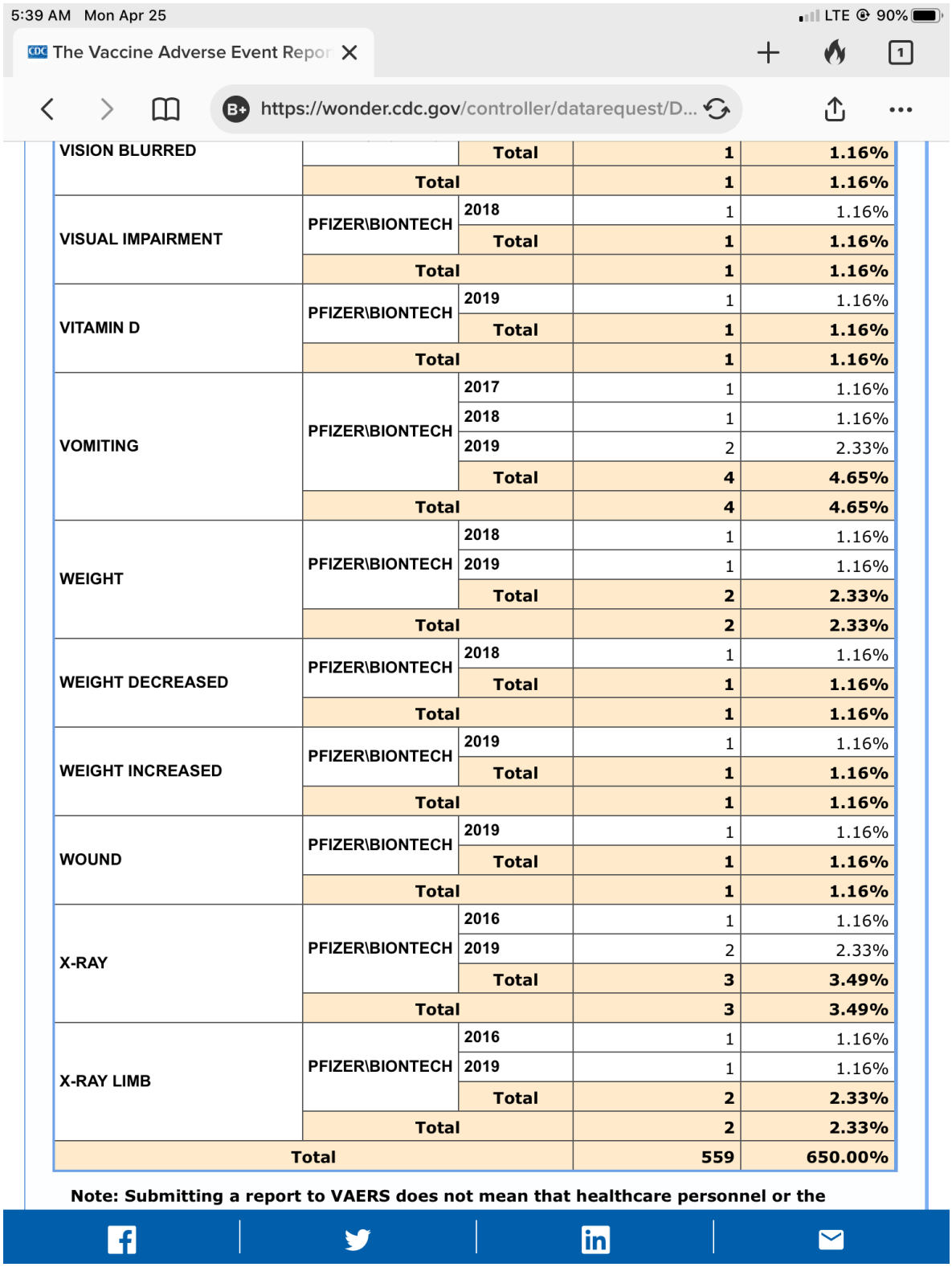
Figure 12: Death, Acute myocardial infarction, pulmonary embolism from all Pfizer vaccines reported in VAERS 2015-2019 screenshot.

6) These final two screenshots show the first and last pages of a VAERS request for all symptom complaints in VAERS for *all* Pfizer vaccines administered from 2015 through 2019, before the COVID-19 vaccine was available. The total of reported symptoms complaints was only 559 for those five years. In contrast, there were 584 reports of Deep Vein Thrombosis in just the first three months of 2021, all related to Pfizer's COVID-19 vaccine. The most frequent complaints in this report before 2020 were for headaches, weakness, and muscle pain, all with less than 20 examples. In contrast, as shown in Figure 1 above, there were 27,000 headaches reported in association with Pfizer's COVID-19 vaccine.
[https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=8EE87DA751B1EC168FBD8432A2E6]



Symptoms	Vaccine Manufacturer	Year Vaccinated	Events Reported	Percent (of 86)
ABDOMINAL DISCOMFORT	PFIZER\BIONTECH	2016	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
ABDOMINAL PAIN	PFIZER\BIONTECH	2019	3	3.49%
		Total	**3**	**3.49%**
	Total		**3**	**3.49%**
ABDOMINAL PAIN LOWER	PFIZER\BIONTECH	2016	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
ABDOMINAL PAIN UPPER	PFIZER\BIONTECH	2016	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
ACOUSTIC STIMULATION TESTS	PFIZER\BIONTECH	2019	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
ACOUSTIC STIMULATION TESTS ABNORMAL	PFIZER\BIONTECH	2019	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
AGEUSIA	PFIZER\BIONTECH	2019	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
ALOPECIA	PFIZER\BIONTECH	2018	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**

Figure 13: All symptoms, all Pfizer vaccines reported in VAERS 2015-2019 screenshots, first page of report.



VISION BLURRED		**Total**	**1**	**1.16%**
	Total		**1**	**1.16%**
VISUAL IMPAIRMENT	PFIZER\BIONTECH	2018	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
VITAMIN D	PFIZER\BIONTECH	2019	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
VOMITING	PFIZER\BIONTECH	2017	1	1.16%
		2018	1	1.16%
		2019	2	2.33%
		Total	**4**	**4.65%**
	Total		**4**	**4.65%**
WEIGHT	PFIZER\BIONTECH	2018	1	1.16%
		2019	1	1.16%
		Total	**2**	**2.33%**
	Total		**2**	**2.33%**
WEIGHT DECREASED	PFIZER\BIONTECH	2018	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
WEIGHT INCREASED	PFIZER\BIONTECH	2019	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
WOUND	PFIZER\BIONTECH	2019	1	1.16%
		Total	**1**	**1.16%**
	Total		**1**	**1.16%**
X-RAY	PFIZER\BIONTECH	2016	1	1.16%
		2019	2	2.33%
		Total	**3**	**3.49%**
	Total		**3**	**3.49%**
X-RAY LIMB	PFIZER\BIONTECH	2016	1	1.16%
		2019	1	1.16%
		Total	**2**	**2.33%**
	Total		**2**	**2.33%**
Total			**559**	**650.00%**

Note: Submitting a report to VAERS does not mean that healthcare personnel or the

Figure 14: All symptoms, all Pfizer vaccines reported in VAERS 2015-2019 screenshots, last page of report.

Steve Kirsch noted, “The CDC knew in January 2021 that the vaccines were unsafe, but they said nothing.” [https://stevekirsch.substack.com/p/the-cdc-knew-in-January-2021-that?s=r] The evidence identified from VAERS that has been identified in the reports shows conclusively that Pfizer, the CDC, and the FDA knew that severe neurological and blood clotting harms were resulting from the mRNA vaccines on grand scale. To date, they remain silent and are not taking action to stop the life-altering and sometimes fatal outcomes from Pfizer’s COVID-19 vaccine.

Report 19: "Effects of N1-methyl-pseudouridine in the Pfizer mRNA Vaccine" – Daniel B. Demers, PhD – Team 5.

Introduction

The use of messenger RNA (mRNA) vaccines has been developing since 1990. Historically, there have been three significant problems associated with mRNA vaccines. First, it has always been a challenge for vaccine developers to get the desired mRNA into the cells of choice (the delivery problem). Second, introducing a foreign RNA (the vaccine mRNA) into a patient causes their body to initiate an innate immune response thereby causing pathogenesis when there actually was no infection (the immunogenicity problem). And third, RNAs are rapidly degraded by ribonucleases (RNases) which are enzymes that degrade RNA. These RNases are found virtually everywhere which not only hinders development, but also makes it difficult to get a desired mRNA in a vaccine to stay around long enough to elicit the desired response (the degradation problem). There are many summaries of these historical facts (Morais et al., 2021; Jain et al., 2021; Kariko et al., 2008).

The claim among mRNA vaccine manufacturers and some scientists is that the three problems cited above have been solved; but have they?

Both Pfizer and Moderna claim that they solved these problems by encasing the mRNA inside of a lipid nanoparticle (LNP) and by modifying the mRNA through the substitution of N1-methylpseudouridine for the nucleotide uridine (Morais et al., 2021; Jain et al., 2021; Nance and Meir, 2021; Pardi et al., 2018; Andries et al., 2015). The use of LNPs allegedly solves the delivery problem by getting the vaccine's modified mRNA into the cells and helping to protect the mRNA molecules from degradation during their trip from injection site to target cells. Their use of LNPs is another matter to be addressed in a subsequent report.

The use of a modified uridine (N1-methylpseudouridine) to replace uridine was supposed to solve the last two problems: the inherent immunogenicity of foreign mRNAs and degradation of the mRNA. These matters are the topic of this report.
Does the use of a modified uridine (N1-methylpseudouridine) solve the problem of the immune response to a foreign RNA such as the vaccine delivered modified mRNA and premature degradation of the vaccine delivered mRNA?

It is difficult to dissect these two issues (mRNA immunogenicity and degradation) because they are so interconnected. But first, what is N1-methylpseudouridine and what does it do?

Modified Uridine

In nature, modified uridines (such as pseudouridine and N1-methylpseudouridine) incorporated into RNA allow the body's immune system to distinguish "self" from "non-self"; that is, the body's own RNA molecules (self) from foreign (non-self) RNA molecules (Kariko et al 2005). mRNA-based

vaccine development was hindered for years because the body recognized the vaccine mRNA as foreign and initiated an immune response to eliminate the foreign material. Vaccine manufacturers needed a way to suppress that immune response if mRNA vaccines were to be used. But what are the consequences of suppressing the body's first line of defense, innate immunity?

Pseudouridine was first described in yeast in 1957 (Davis and Allen, 1957) and named the fifth nucleotide, a name it still carries (Borchardt et al., 2020). Pseudouridine is an isomer of uridine; that is, pseudouridine has the same identical atomic composition as uridine but with a slightly different structure. For pseudouridine, although this change is structurally minor, when incorporated into an RNA molecule by the cell in a *strategic and specific* manner, the changes in properties it imparts to RNA molecules are major.

Besides being involved in gene expression and protein production, natural conversion of uridine to pseudouridine stabilizes the molecule and protects it from degradation by RNases and helps it to evade immune detection (Borchardt et al., 2020).

There is considerable evidence that the use of pseudouridine in vaccine mRNA does in fact protect the mRNA molecule from RNases and thus, slows its degradation and can suppress the unwanted immune response mechanism (Morais et al., 2021; Borchardt et al., 2020; Eyler et al., 2019; Zhao et al., 2018; Kariko et al., 2008). In addition, but not always mentioned, is that pseudouridine increases protein (including spike protein) production (Svitkin et al., 2017). Use of pseudouridine was justified by researchers on the basis that it is a naturally occurring modified nucleotide within our cells and gets *strategically and specifically* incorporated into many RNA molecules including mRNA. It is known to be involved in multiple aspects of gene expression and protein production (Morais et al., 2021).

However, pseudouridine contributes a universal base character to the nucleotide. Whereas uridine (U) normally base pairs only with adenine (A), pseudouridine exhibits a "wobble" character to it and will allow uridine to base pair with adenine (A), guanine (G), cytosine (C) and uridine (U). These natural modifications in an RNA molecule evidently contribute to its function (Morais et al., 2021; Parr et al., 2020; Svitkin et al., 2017). However, in a vaccine mRNA this would be problematic as it would change the amino acid sequence of the resulting protein, in this case, the spike protein. For a more thorough description of base pairing see the YouTube video -- https://www.youtube.com/watch?v=7AtO8DuWsck.

The vaccine manufacturers addressed the "wobble" characteristic of pseudouridine by substituting N1-methylpseudouridine into their mRNA construct rather than pseudouridine. N1-methylpseudouridine is different from uridine or pseudouridine but has been shown to demonstrate the beneficial attributes of pseudouridine that the manufacturers sought (protection from degradation, evasion of immune detection, increased protein production, molecule stability) while

eliminating the "wobble" character that pseudouridine exhibited (Svitkin et al., 2017; Parr et al., 2020; Morais et al., 2021; Nance et al., 2021).

N1-methylpseudouridine is also naturally occurring but with much lower frequency, and structurally and chemically, it differs considerably from pseudouridine. N1-methylpseudouridine has an added methyl group (CH3) and this modification probably contributes to its higher affinity for pairing with adenine, a much-desired attribute for a vaccine mRNA because it is the normal pairing (Morais et al., 2021).

But in nature, modified nucleotides are *strategically and specifically* inserted and required for proper folding, stability and accurate decoding of RNA molecules (Wurm et al., 2012). Wu et al. (2015) found that abolishing specific pseudouridines in another type of RNA (ribosomal RNA or rRNA) severely affects ribosome function.

Borchardt et al. (2020) used mass spectrometry to analyze mRNA pseudouridine content. They found that pseudouridine was present at 0.2 to 0.6% of total uridine in mRNA from human HEK293T cells (a human immortalized cell line). They hypothesized that mRNA pseudouridylation controls metabolism in response to cellular conditions, and stress conditions induce changes in expression of these modified nucleotides. The placement of pseudouridines affects the RNA backbone conformation and stability of base pairs. Furthermore, pseudouridine alters RNA-protein interactions for several RNA binding proteins (RBPs) that regulate RNA processing. Borchardt et al. (2020) states that "artificial pseudouridylation of a single position can inhibit function." Furthermore, they state that "pseudouridine is not always treated as a uridine by the ribosome and could affect translation of the protein."

Therefore, given that the amount of pseudouridine is relatively small in nature (0.2 to 0.6% of total uridine in mRNA), and that the points of pseudouridine insertion are *strategic and specific,* and that even this amount of pseudouridylation is not well understood, what would be the anticipated outcome of total replacement of a foreign mRNA uridine population with an even more rare, modified nucleotide, N1-methylpseudouridine? That is precisely what Pfizer did in its mRNA vaccine. They did not strategically and specifically replace some uridines in their already modified mRNA (already producing two amino acid substitutions in the spike protein), they replaced **all** uridines in the mRNA (Nance et al., 2021). But this issue is not mentioned in the Pfizer document 2.4 NONCLINICAL OVERVIEW (https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf) or in two papers published as a result of Pfizer's Phase 1/2 trials (https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf).

The knowledge base of pseudouridine is limited. Borchardt et al. (2020) summarizes it well; "Despite intensive investigation of the structural and biochemical effects of pseudouridine in various

systems, the biological role of most endogenous pseudouridine remains unknown." They continue, "Pseudouridine likely affects multiple facets of mRNA function including reduced immune stimulation by several mechanisms, prolonged half-life, as well as potentially deleterious effects on translation fidelity and efficiency." Furthermore, the authors stated, "The functions of endogenous pseudouridine in mRNA remain to be discovered." They go on to state that RNA pseudouridylation could have widespread effects on RNA metabolism and gene expression and that "much remains to be known."

Given that there is still so much to learn about how endogenous pseudouridine affects biological systems, we must ask ourselves what effects N1-methylpseudouridine might have on these same biological systems, especially considering that so little is known about N1-methylpseudouridine. Afterall, the enzyme, N1-methyltransferase, the enzyme that catalyzes the synthesis of N1-methylpseudouridine, was only identified in 2012 (Wurm et al., 2012). Studies on N1-methylpseudouridine began in earnest in 2015 (Andries et al., 2015). The history of pseudouridine dates back to the 1950s whereas the history of N1-methylpseudouridine only dates back to 2012. Obviously, science has barely scratched the surface of N1-methylpseudouridine and its effects on biological systems.

The incorporation of N1-methylpseudouridine in a mRNA vaccine is obviously not *strategic and specific* as in natural incorporation. Rather, Pfizer used a shotgun approach, and they had no idea what the ramifications and unintended consequences of such a modification would be. How are the folding, function, localization and clearance of the subsequent protein affected? What does such a massively modified foreign mRNA do to the delicate balance of cells and bodies (homeostasis) that receive it?

To date, there has been nothing identified in nature that resembles the Pfizer modified mRNA, nothing even close. How does this Pfizer modified mRNA interact with the cell' protein machinery? Where does it localize within the human body? How long does it last? Are there long-term toxicity, carcinogenicity or pharmacological concerns? None of this has been studied. In fact, there is no mention of pseudouridines or N1-methylpseudouridines in the Pfizer document 2.4 NONCLINICAL OVERVIEW (https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf).

Good science demands answers to these important questions, and the answers should have been obtained before injecting hundreds of millions of people globally (billions of doses) with such an experimental substance.

Immunogenicity: Solution or Problem?

Vertebrates, including humans, have evolved an immune system to eliminate pathogens. That system has two major branches, innate and adaptive immunity. The innate immune system is the

body's first line of defense. Frizinsky et al. (2019) states that it is "more than the first line of defense, it is crucial to the survival of the host." The body reacts quickly to foreign RNA molecules by producing interferon, cytokines and chemokines (Kang and Compans, 2009; Pardi et al., 2018). These molecules, and others, are released by the cells to protect the body through cell signals and pro-inflammatory responses. They may also impact the adaptive immune response which is the second line of defense. This report will only consider the innate immune response to a modified mRNA invader.

The effects of innate immunity on vaccine mRNA are incompletely understood but there does seem to be agreement that it prevented traditional mRNA vaccines from being used because the foreign RNA gets cleared by the immune system (Kariko et al., 2005; Svitkin et al., 2017; Borchardt et al., 2020; Parr et al., 2020; Morais et al., 2021; Jain et al., 2021). Pardi et al. (2018) noted that some mRNA-based vaccine platforms induce interferon which is associated with inflammation and potentially autoimmunity, edema, blood coagulation and thrombosis. It also increases cytotoxicity leading to apoptosis (cell death) which of course reduces the effectiveness of the vaccine.

Pepini et al. (2017) stated that "activation of the innate immune response by RNA vaccines is potentially a double-edged sword." On the one hand, with activation of an innate immune response comes release of interferon and cytokines which facilitate the adaptive immune response (which might be needed later). On the other hand, it may, as discussed by Pardi et al. (2017), cause an inflammatory response to the vaccine leading to flu-like symptoms and potentially autoimmunity, edema, blood coagulation and thrombosis, as well as degradation of the vaccine mRNA. As early as February 2020, at that critical time of conception of the Pfizer mRNA construct, it was reported that "the influence of modified bases on the function of a synthetic RNA is poorly understood" (Parr et al., 2020). But it was known that modified RNA, containing pseudouridine or N1-methylpseudouridine, did suppress innate immunity. Aside from helping the vaccine's modified mRNA to survive in the body, the consequences of suppressing innate immunity simply were not known.

Despite this lack of knowledge involving suppression of the innate immune system, Pfizer still chose to use mRNA modified with N1-methylpseudouridine (Morais et al., 2021; Nance et al., 2021). It was a tradeoff between maintaining the body's innate immunity (its first line of defense) and ability to degrade and deactivate the vaccine's mRNA, and a good adaptive immune response (the second line of defense) needed if a SARS-CoV-2 infection were subsequently encountered (Parr et al., 2020; Ivanova et al., 2021; Seneff et al., 2022). Although there is still much to learn about compromised innate immunity, it has for many years been recognized as a vital part of the adaptive immune system, which is critical in responding to an infection. Dysregulated innate immune responses are considered lethal early in life and many diseases are linked to malfunction in this system (Frizinsky et al., 2019).

It was by design that N1-methylpseudouridine, as well as lipid nanoparticles, were used by Pfizer to modify the SARS-CoV-2 mRNA. As discussed above, they were specifically used to prevent degradation of the mRNA and suppress the innate immune response (Morais et al 2021, Nance et al 2021, Wadhwa et al 2020; Borchardt et al., 2020).

Already, the approach of suppressing the innate immune response in COVID-19 vaccinees is proving problematic. Suppressing the body's innate immune response downregulates critical systems related to cancer surveillance, infection control and cellular homeostasis (ability to maintain a steady state of chemical and physical conditions). Vaccinees are unable to upregulate their interferons (as described above) which affect numerous downstream sequences to protect the body (Pepini et al., 2017; Pardi et al., 2017; Parr et al., 2020; Liu et al., 2021).

Ivanova et al. (2021) evaluated the immune response of patients with acute COVID-19 (unvaccinated) and healthy adults after receiving the Pfizer BNT162b2 vaccine. Although infection with SARS-CoV-2 and vaccination have both been shown to stimulate an immune response, that response in the two groups was qualitatively different. In the COVID-19 patients the immune response was characterized by augmented interferon signaling and upregulation of genes associated with cytotoxicity. These responses were missing in the vaccinated group. The antibody and cellular profiles between the two groups also differed. The vaccine group elicited reduced levels of IgA and IgM antibodies compared to the COVID-19 group (Ivanova et al., 2021). This was also observed by Röltgen et al. (2022).

Another indication of impaired immune response is increased cell damage. Jain et al. (2021) reported on a study of 63 patients with "coronavirus disease 2019 vaccination-associated myocarditis (C-VAM)". All patients were less than 21 years of age, 92% were male, all had an mRNA vaccine and except for one patient, all presented after the second dose. This is not surprising considering that Avolio et al. (2021) demonstrated that SARS-CoV-2 spike protein may prompt damage to cardiac pericytes (part of microcirculation) *in vitro*. The Vaccine Adverse Event Reporting System (VAERS) reported 8,090 heart disorders associated with COVID-19 vaccines in 2021 which accounts for 97.7% of all vaccine adverse events in that year (https://vaers.hhs.gov/about.html).

Degradation: Solution or Problem?

Röltgen et al. (2022) reported that they found vaccine mRNA in germinal centers (secondary lymphoid organs including lymph nodes and spleen which are important for B-cell activation) up to 2 months after a second dose. Mauger et al. (2019) also demonstrated that increased guanine-cytosine (GC) content (a feature of the Pfizer modified mRNA) as well as modified nucleotides such as N1-methylpseudouridine could extend the mRNA half-life and as a result, increase protein production.

Pfizer employed all of the known methods ((5'-cap, 5'-UTR, sequence modification, 3'-UTR and a 3'poly A tail) to prevent degradation and thereby increase the half-life of their mRNA (Mauger et al., 2019; Wadhwa et al., 2020; Nance et al., 2021). Thus, it is not surprising that clearance of the vaccine mRNA is delayed and can be found 2 months post-injection (Röltgen et al., 2022). Yet, in the Pfizer document 2.4 NONCLINICAL OVERVIEW (p. 20, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf) Pfizer states that "RNA is degraded by cellular RNases and subjected to nucleic acid metabolism. Nucleotide metabolism occurs continuously within the cell, with the nucleoside being degraded to waste products and excreted or recycled for nucleotide synthesis. *Therefore, no RNA or protein metabolism or excretion studies will be conducted*" (emphasis added). The modifications to the SARS-CoV-2 mRNA made by Pfizer were clearly made to prevent degradation and extend the half life of the vaccine's mRNA (McKernan et al., 2021; Seneff et al., 2022; Nance et al., 2021; Morais et al., 2021; Mauger et al., 2019; Svitkin et al., 2017; Kierzek et al., 2013), yet Pfizer ignored this well-established fact and contradicted its own development logic and decided that "no RNA or protein metabolism or excretion studies will be conducted" (p. 20, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf). And the FDA accepted that contradiction in Pfizer's science.

Spike Protein Production

One final issue related to the Pfizer mRNA vaccine to be briefly mentioned here is the enhanced spike protein production, generated from the vaccine mRNA. It is included here because it is, in part, related to the use of N1-methylpseudouridine in the vaccine's modified mRNA. There are numerous other issues, but they exceed the scope of this report. See Seneff et al. (2022) for a thorough discussion.

A side effect of N1-methylpseudouridine substitution is enhanced translation of mRNAs (enhanced protein production) (McKernan et al., 2022; Morais et al., 2021; Nance et al., 2021; Parr et al., 2020; Mauger et al 2019; Svitkin et al., 2017; Kariko et al., 2008). What problems are associated with overproduction of spike protein?

Brun et al. (2020) reported the process by which spike protein (S) is processed within the host cell and soluble S1 subunit is secreted into the extracellular space via lysosomes. Mishra et al. (2021) reported that excess spike protein causes microRNA (miRNA, a special type of RNA important in cellular regulatory function) to be exported out of the cells via exosomes. These released microRNAs get transported to distant tissues and organs, including the brain and central nervous system (CNS) where they are internalized and initiate a cascade of deleterious effects (Mishra et al., 2021).

MicroRNAs are being recognized as an enormously important component of gene expression and regulation and are associated with many diseases as well as immune response (O'Brien et al., 2018;

Zhang et al., 2021). By the way, SARS-CoV-2 genome, including the spike protein mRNA, have been shown to encode their own miRNAs, some of which interact with human miRNAs (Liu et al., 2020). This undeniably important biomolecule was not mentioned by Pfizer either.

Conclusion

To summarize, Pfizer utilized lipid nanoparticles and a modified mRNA in which all natural uridine nucleotides were replaced with a rarely encountered nucleotide, N1-methylpseudouridine. While it solved their problems of RNA delivery, immunogenicity and degradation, it created some new problems. While uridine substitution was found to reduce the body's immune response to the foreign RNA and protect the mRNA from degradation, there are adverse effects from this strategy.

There is practically no scientific data available on how total uridine substitution in an mRNA will affect the delicate balance of the cellular and bodily physiology of the host and what downstream effects may be initiated. Yet Pfizer conducted no studies on this issue.

Suppressing the body's innate immune system also has downstream consequences, particularly if a SARS-CoV-2 infection is subsequently encountered. Increasing the stability and half-life of the vaccine mRNA, along with increasing its translation, means increased production of the spike protein which, as it turns out, is itself a cause of pathogenesis.

Problems with the Pfizer vaccine design and failure to adequately investigate their effects on the delicate cellular systems of the human body are already manifesting themselves. These problems are summarized in VAERS (https://vaers.hhs.gov/about.html). The long list of adverse events is a reflection of these issues.

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Report 20: "Cytokines: A Cause for Concern in Pregnant and Nursing Women?" by Elon Espey, PMHNP, FNP, BC – Team 5.

Cytokines and their effects have been in the headlines as long as Covid-19 has been with us. But what do we know about cytokines, and what do we know about the effects of cytokines on pregnant and nursing women? How are cytokines related to mRNA vaccines and breast milk? This essay explores these questions and more.

What are cytokines? Cytokines are a large, diverse family of small proteins or glycoproteins that play an important role in regulating inflammatory and immune responses. According to Manoylov, M. K. (2020) these proteins are produced by many different immune cells, such as neutrophils, mast cells, macrophages, B-cells, and T-cells. Cytokines radiate out from immune cells and bind to specific receptors on other immune and non-immune cells. There the cytokines signal to the cell how it needs to behave, which is why cytokines are often referred to as "messenger cells" because they carry a "message" with them as they travel through the body. For instance, they may give the message to increase inflammation or pain. Nearly every organ of the body contains cells with cytokine receptors. Some of the various types of cytokines include interleukins (IL 1-13), interferons (α, β, and γ), tumor necrosis factor (TNF), and transforming growth factor (TGF-β).

How do cytokines work? When a pathogen or harmful substance enters the body, immune cells, cytokines, and organs work together to respond. The first cell to notice the pathogen directs all the other cells by creating and sending out messages (cytokines) to the rest of the cells or organs, which respond as directed. Because cytokines derived from the immune system (immunokines) are toxic to cells, they have been used against certain types of cancer. However, their clinical usefulness is limited due to their short half-life and their wide ranging and unpredictable side effects (Farlex Partner Medical Dictionary, 2012).

Cytokines play a broad role in helping the immune system respond to diseases and drugs which modulate their effect and have led to some beneficial therapies. Cytokines may be "good" when stimulating the immune system to fight a foreign pathogen, attack tumors, or reduce an immune response, such as inflammation in patients with multiple sclerosis. On the other hand, cytokines may be "bad" when their expression causes inflammatory diseases. Therapeutic modulation of cytokine expression can tell the "good" cytokines to generate or control the immune system and block the "bad" cytokines to prevent damaging inflammatory events. However, care must be exercised, as some antibody therapeutics can cause "ugly" cytokine release which can be deadly (Ramani, T., et al., 2015).

A severe immune reaction in which the body releases too many cytokines into the blood too quickly is known as a cytokine storm. A cytokine storm can occur as a result of infection, autoimmune condition, or other disease, or even after treatment with some types of immunotherapies (National

Cancer Institute, 2022). This phenomenon was first described in 1993 as an uncontrolled inflammatory response caused by an excess number of cytokines being released, leading to over-activation of other immune cells like T-cells, macrophages, and natural killer cells. The uncontrolled activity of these cells can lead to tissue damage, organ dysfunction, and sometimes death. They were even thought to have been responsible for the high number of deaths in young people during the 1918 flu pandemic (de Wit, E., et al., 2018).

How do cytokines affect pregnant and nursing women? A literature review of "Inflammatory Breast Diseases during Lactation: Health Effects on the Newborn" was conducted in 2008 by Wöckel, A., et al. The review revealed that an imbalance in cytokines in breast milk may have severe consequences for the child, which in turn affects the child's development. On one hand, a rise in cytokines in breast milk is useful to activate a mechanism of maternal self-defense against infectious processes and could also be useful in breastfed infants in order to activate or stimulate their immunity. However, it is possible that a permanent oversupply of cytokines leads to an excessive stimulation/threat of the child's immune system and subsequent onset of diseases. The review further showed evidence of increased cytokines in breast milk during inflammatory processes and possible pathological effects of these higher cytokine levels on the newborn. Further study was recommended.

A study conducted by Dammann, O. and O'Shea, M. (2008) pointed out that evidence from epidemiological studies and experiments over more than 30 years in animals indicated that infection remote from the brain is a potential cause of cerebral white matter damage in human neonates. Since then, a large body of evidence suggests a link between infection and brain damage involving various mediators of inflammation, including cytokines, chemokines, and immune cells. These inflammatory mediators are also involved in brain-damaging processes that follow energy deprivation, as may occur with intrapartum asphyxia (deprivation of oxygen in a newborn). Equally as important is the role of cytokines in modulation of inflammation and repair after inflammation-related brain damage. The researchers suggest that strategies to reduce the frequency and extent of pre- and perinatal brain damage may derive from therapeutic interventions which either enhance the production or activity of certain "damage protectors" (e.g., anti-inflammatory cytokines) or inhibit the production or activity of specific "damage mediators" (e.g., inflammatory cytokines).

According to Pickler, R., et al. (2010), there is a growing body of literature supporting the relationship between maternal inflammation with preterm birth and adverse neonatal outcomes. Mediators of inflammation, most notably proinflammatory cytokines, have been implicated as having an association with adverse neonatal outcomes. Lyon, D., et al. (2010) conducted a systematic review of evidence from human studies for the association of levels of cytokines in the blood and preterm labor and adverse early fetal outcome. The most consistent finding was increased levels of proinflammatory cytokines; particularly interleukin (IL) 6, IL-1β, and tumor necrosis factor α (TNFα) were associated with preterm birth. A follow up review by Pickler, R., et al. (2010) of

evidence from human studies on the association of cytokine levels in blood with two early adverse outcomes in preterm infants found early infection and increased risk of neurological damage. The review revealed that the proinflammatory cytokines most frequently linked with sepsis are in the IL-1 family as well as TNFα and IL-6. The proinflammatory cytokines most frequently associated with neurologic insult in the reviewed studies were IL-1β, IL-6, and IL-8. In all cases where IL-1β was studied, the levels were increased when there was a neurologic insult.

Other studies reveal a correlation with miscarriages and cytokine levels. Calleja-Agius, J., et al. (2011) conducted an observational study over a 1-year period of 94 Maltese women presenting with threatened abortion (TM) compared to 564 age-matched controls from the National Obstetric Information System (NOIS) of Malta. A pilot study was carried out with subgroups of 10 women with TM (n=10), non-pregnant women (n=12), normal pregnant controls (n=9), and women presenting with missed miscarriage (n=11), whose plasma levels of β-human chorionic gonadotropin (β-hCG), tumor necrosis factor α (TNFα), interferon γ (IFN γ), interleukin-6 (IL-6), interleukin-10 (IL-10), and TNF receptors 1 (R1) and 2 (R2) were measured. Of the 94 women with TM, 25 (26.6%) proceeded to complete miscarriage and had a significantly higher incidence of antepartum hemorrhage ($p<0.005$), preeclampsia ($p<0.05$), fetal growth restriction ($p<0.05$), premature labor ($p<0.001$), and retained placenta ($p<0.005$). Significantly ($p<0.05$) higher level of TNFα and lower levels of TNF R2 were found in the TM subgroup compared to non-pregnant controls. The ratio of TNFα/IL-10 was significantly ($p<0.05$) higher and the β-hCG levels were significantly lower ($p<0.01$) in missed miscarriages and non-pregnant subgroups than in TM and normal pregnant controls. The IFNγ/1L-10 and IFNγ/1L-6 were significantly ($p<0.001$) different between the four subgroups with the lowest level found in the TM group. No similar gradient was found for the TNFα/1L-6 ratio. Therefore, it was concluded that changes in levels of cytokines could help predict and prevent the development of some of these complications.

Recently, a study conducted at the University of Massachusetts by Narayanaswamy, V., et al. (2022) found that immune responses to mRNA Covid-19 vaccination were present in most women's breast milk. The milk reportedly neutralized the spike protein in four (4) variants of concern, with the potential to confer passive immunity to the breastfed infant against SARS-COV2. The study measured levels of 10 key cytokines in milk of the 26 vaccinated lactating women who completed a questionnaire on side effects. The levels of IFNγ were significantly higher in milk provided after the first dose and after the second dose as compared to milk provided before receiving the vaccine. For women who reported side effects (n=13), compared with samples provided before vaccinations, the levels of IFNγ increased by approximately 2.5-fold in samples provided after the first dose and by more than 20-fold in samples provided after the second dose. Overall, among women who reported any side effects, the levels of IFNγ were significantly higher in milk after vaccination than in milk provided before receiving the vaccine. Among the women who reported no side effects after either the first or second dose (n=13), compared with samples provided before vaccination, the median levels of IFNγ increased by approximately 2-fold in samples provided after the first dose and by 3-

fold in samples provided after the second dose. Levels of five of the seven other tested cytokines were comparable across the three time points; levels of the remaining two cytokines were not consistently detectable. While the study showed antibodies to SARS-COV2 being transferred via breast milk, they also found that levels of antibodies/cytokines correlated with vaccine side effects that mothers experienced.

The above University of Massachusetts study has since been heavily cited and reported on frequently in support of vaccinating women while pregnant and lactating. One of the researchers, K. F. Arcaro was quoted as saying "women who did feel sick from the vaccine was [sic] associated with greater antibodies in the infant stool...so you might have felt badly, but that was a benefit for your infant" (Science Daily, 2022).

A cause for concern? Clearly cytokines are a diverse group of protein molecules that can be both beneficial and harmful. Increased levels of certain cytokines are shown to have deleterious effects in infants when passed from the mother's milk during other (non-Covid-19) inflammatory events. So why would increased cytokine levels following maternal vaccination with mRNA Covid-19 "vaccines," that are also noted to be associated with increases in maternal side effects, be any less harmful or cause for concern?

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Report 21: "Dr. Fernando Polack: Real Person or Ghost?" – Team 5.

Who is Dr. Fernando Polack, and where does he work? Vanderbilt in Nashville? No. Johns Hopkins in Baltimore? No. Buenos Aires? Not that I can find.

In this brief foray into Dr. Polack's background, he appears to be more of a well-funded ghost than a real person.

Program notes from CIPP XVI in Lisbon Portugal dated June 22-25, 2017, reads:

*"**Dr. Fernando Polack** (https://www.cipp-meeting.org/CIPPXVI/id-82-fernando-p-polack.html)is a Specialist in Pediatric Infectious Diseases, graduated with Honors from the University of Buenos Aires in 1990. Dr. Polack completed residency training at the French Hospital in Buenos Aires and at William Beaumont Hospital in Michigan followed by a post-doctoral fellowship at Johns Hopkins University. Dr. Polack is the **Cesar Milstein Professor in the Department of Pediatrics at Vanderbilt University** and the **Scientific Director of the INFANT Foundation in Buenos Aires which coordinates a network of 26 hospitals in Argentina.** Dr. Polack has led numerous scientific manuscripts in reputed journals, including New England Journal of Medicine (NEJM), Nature Medicine, Journal of Experimental Medicine and Proceedings of the National Academies of Sciences (PNAS), among others. His work is funded by the Bill & Melinda Gates Foundation, the National Institutes of Health (NIH), the Thrasher Research Fund, the Optimus Foundation and other international organizations."*

(https://www.cipp-meeting.org/CIPPXVI/faculty-members.html)

Dr. Polack is listed as Cesar Milstein Professor in

the Department of Pediatrics at Vanderbilt University.

"PLENARY SESSION

08:30 – 10:00 – Room A

Chairmen:
Paulo Camargos – Belo Horizonte, Brazil
Renato Stein – Porto Alegre, Brazil

1. *Maintaining Respiratory Health in Resource-poor Populations.*
   Catherine Byrnes – Auckland, New Zealand
2. *Mortality Associated with Severe Viral Infections in Early Life.*
   Fernando Polack – Buenos Aires, Argentina
3. *Food Allergy for Respiratory Pediatricians.*
   Adnan Custovic – London, UK

Respiratory Viruses and Their Relation to Disease

10:30 – 12:00 – Room B

Chairpersons:
Milagros Salvani Bautista – Manila, Philippines
Antonio Martinez Gimeno – Toledo, Spain

1. *Viral Bronchiolitis in Children.*
   Giovanni Rossi – Genoa, Italy
2. *The Drakenstein Child Health Study: New Insights into Childhood LRTI.*
   Heather Zar – Cape Town, South Africa
3. *Advances in Prevention of RSV Disease.*
   Fernando Polack – Buenos Aires, Argentina"

However, Vanderbilt Department of Pediatrics (https://pediatrics.vumc.org/) has no such faculty member or chaired position.

There is also no listing for Dr. Polack at Vanderbilt Children's Hospital.
(https://www.childrenshospitalvanderbilt.org/doctors?query=Pollack&specialty=128)

Vanderbilt Institute for Global Health (https://www.vumc.org/global-health/) has no listing in Buenos Aires and no record of Dr. Polack.

International Training Programs (https://www.vumc.org/global-health/prior-project-list) through Vanderbilt has no listing for Dr. Polack or for Buenos Aires, past or present.

"INFANT Foundation

This program will provide participants with the opportunity to conduct biomedical translational research or pediatric rotations at hospitals and medical centers in Buenos Aires."

"Fernando received the Award for Excellence in Research and Young Pediatric Investigator by the Pediatric Research Society and the Pediatric Society of the United States; The Thomas and Carol McCann Award in Respiratory Research, from the Johns Hopkins School of Public Health and the Pasteur Mèrieux Connaught Laboratories Fellowship in Pediatrics from the Infectious Diseases Society of America In Argentina, the B'nai B'rith at the Human Rights Award; Louis Pasteur Prize, O.S. Health, National Academy of Medicine and Distinguished Citizen in the Field of Sciences, of the Government of the City of Buenos Aires. He is also a Member of the Argentina 2030 Presidential Council and Honorary Professor, Maimonides University and Doctor Honoris Causa, Antenor Orrego Private University, Trujillo, Peru. In addition, Fernando is a Member of the Society for Pediatric Research (SPR), the American Pediatric Society (APS), the Society of Clinical Investigators (ASCI) of the Committee of the International Respiratory Syncytial Virus Society and

the American Association for the Advancement of Science (AAAS). He is advisor to the Food and Drugs Administration (FDA) Vaccine Safety Committee and Consultant to the World Health Organization (WHO) Pediatric Vaccine Development Committee in Geneva."

Doximity (https://www.doximity.com/pub/fernando-polack-md) gives an office for Dr. Polack in Baltimore:

"Office

600 N Wolfe St
Baltimore, MD 21287

***Phone** (410) 614-3917*

***Summary:** Dr. Fernando Polack, MD is a pediatric infectious disease specialist in Baltimore, Maryland."*

But there are no office hours or listing for Dr. Polack as a staff member at Johns Hopkins. (https://www.hopkinsmedicine.org/profiles/search?query=Polack)

So where does Dr. Polack work? Nowhere that I can find. Following are a few other sources I have searched.

- https://diariodeflores.com.ar/quien-es-fernando-polack-el-director-de-la-fundacion-infant-que-trajo-la-vacuna-que-probara-el-pais-contra-el-coronavirus/
- https://doctor.webmd.com/doctor/fernando-polack-9dc76de1-e317-49cf-a305-2aab73df9851-overview
- https://www.resvinet.org/fernando-polack.html

Yet, Dr. Polack was a major contributor to the Pfizer Phase 3 trial and was lead author of the *New England Journal of Medicine* article presenting results before widespread distribution of BNT162b2. There have been others who have questioned the veracity of the Polack contribution.

- https://threadreaderapp.com/thread/1523617233255436289
- https://stevekirsch.substack.com/p/if-this-isnt-covid-vaccine-clinical?s=r
- https://boriquagato.substack.com/p/are-we-pfinding-pfizer-pfraud-part?r=chkp3&s=r&utm_campaign=post&utm_medium=web
- https://boriquagato.substack.com/p/are-we-pfinding-pfizer-pfraud-part-fa2?r=chkp3&s=r&utm_campaign=post&utm_medium=web
- https://davidhealy.org/fishy-business-in-the-rio-de-la-plata/

The topic of Dr. Polack warrants further investigation given his alleged role in the Pfizer COVID-19 vaccine trials.

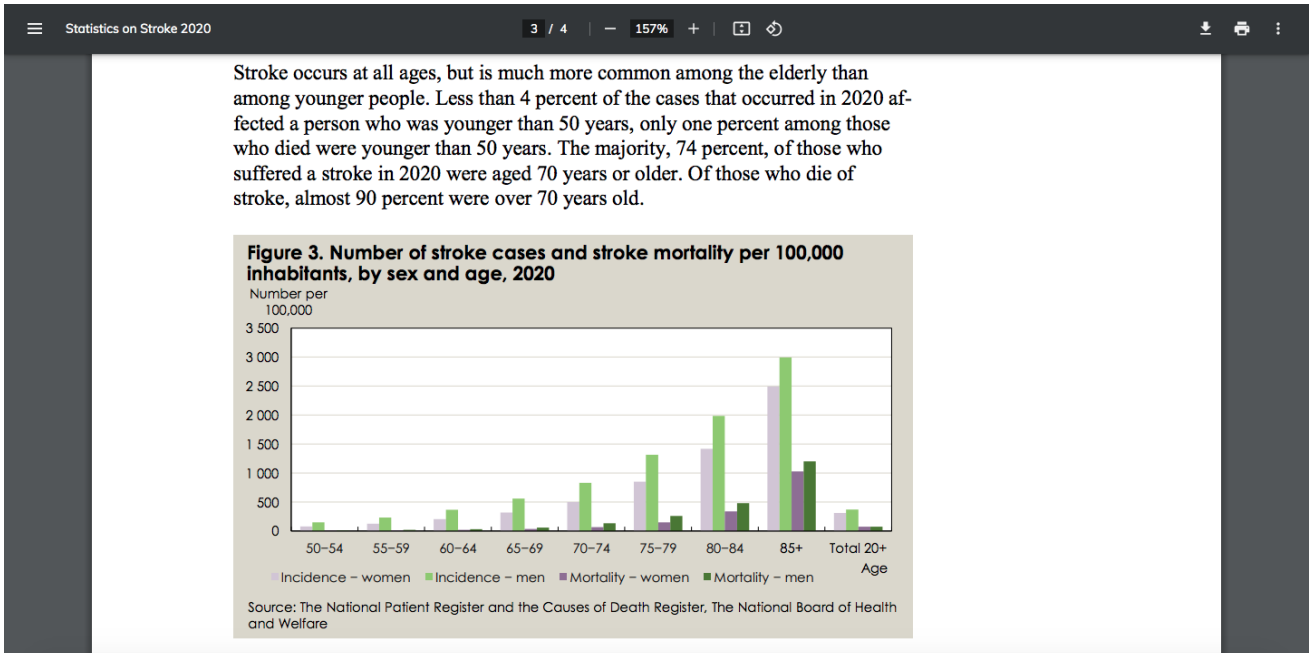
Dr. Polack appears to be a ghost who produces prodigious research funded by National Institutes of Health, the Gates Foundation, and Pfizer.

Report 22: Strokes: "What Did Pfizer Know, and When Did They Know It?" by Melanie Brown – Team 4.

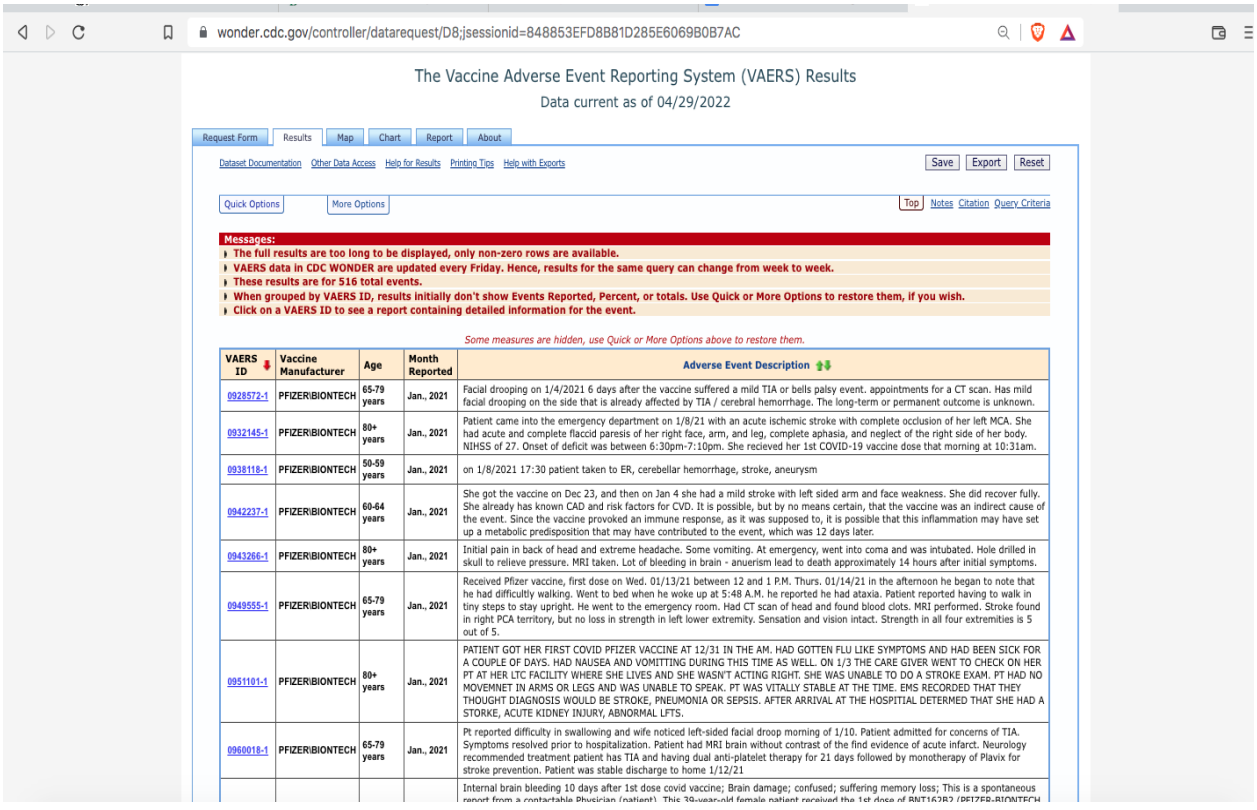
Strokes are a serious, often life-threatening event that can result in death or permanent life altering disability. The incidence of stroke is much more common in the elderly than in younger people. A series of reports are being done to determine what Pfizer knew about any dangers with their vaccine and when did they know it. In this report, a few searches of the Centers for Disease Control and Prevention (CDC) Wonder website Vaccine Adverse Event Reporting System (VAERS) [https://wonder.cdc.gov/controller/datarequest/D8] shows that strokes are a fairly common adverse effect occurring in people of all ages that received the Pfizer vaccine. This report delves into some of these cases to determine if the vaccine may be the cause.

The first report [https://dailyclout.io/what-did-pfizer-know-and-when-did-they-know-it-neurological-harms-concealed/] in this series answering, "What did Pfizer know, and when did they know it?" in regard to the Pfizer BioNTech COVID-19 vaccine, looked at the number of neurological adverse events reported in the VAERS [https://wonder.cdc.gov/controller/datarequest/D8]. It showed the incidence of neurological adverse events reported. Conclusions were startling: the Pfizer vaccine is causing great neurological harm, and this harm was evident early 2021. Pfizer failed to pause the rollout to look at these adverse events.

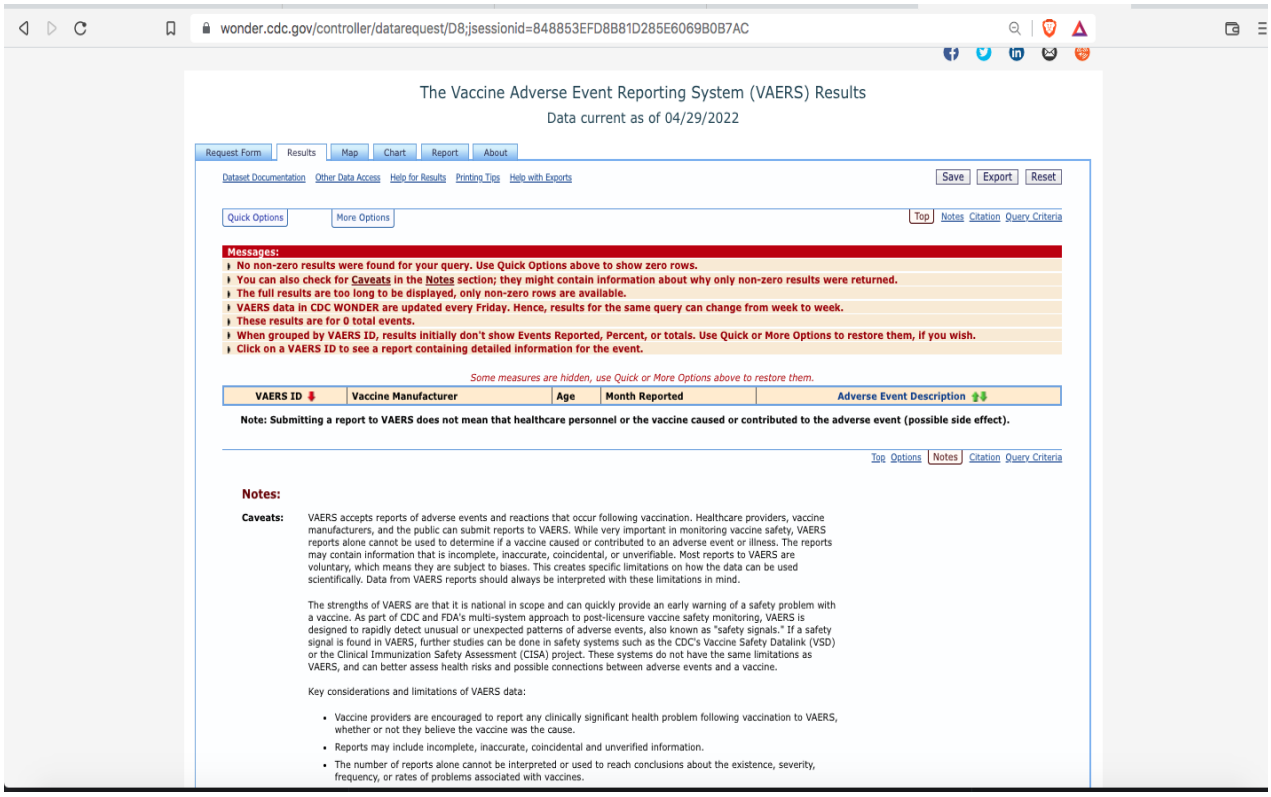
This new report takes a closer look at just one neurological adverse event type: stroke. Strokes are due to a sudden disruption of the blood supply in the brain, usually a clot, blocking the blood supply (ischemic stroke) or by the leaking or rupturing of an artery (hemorrhagic stroke). Ischemic strokes are the most common. Brain cells will die within minutes due to a lack of oxygen during an ischemic stroke or due to damage from the pressure created by bleeding in the case of the hemorrhagic stroke. According to Statistics on Stroke 2020, Socialstyrelsen, 2/12/21, Art No. 2021-12-7644, 1(4), ISSN 1400-3511, less than four percent of the cases that occurred in 2020 affected a person under age 50, and only one percent of them died. [https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/statistik/2021-12-7644.pdf, p. 3] The majority (74%) of those who had a stroke in 2020 were over the age of 70. [https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/statistik/2021-12-7644.pdf, p. 3] Figure 3 from this journal article is depicted in the screenshot below clearly showing the incidence of stroke in different age groups.



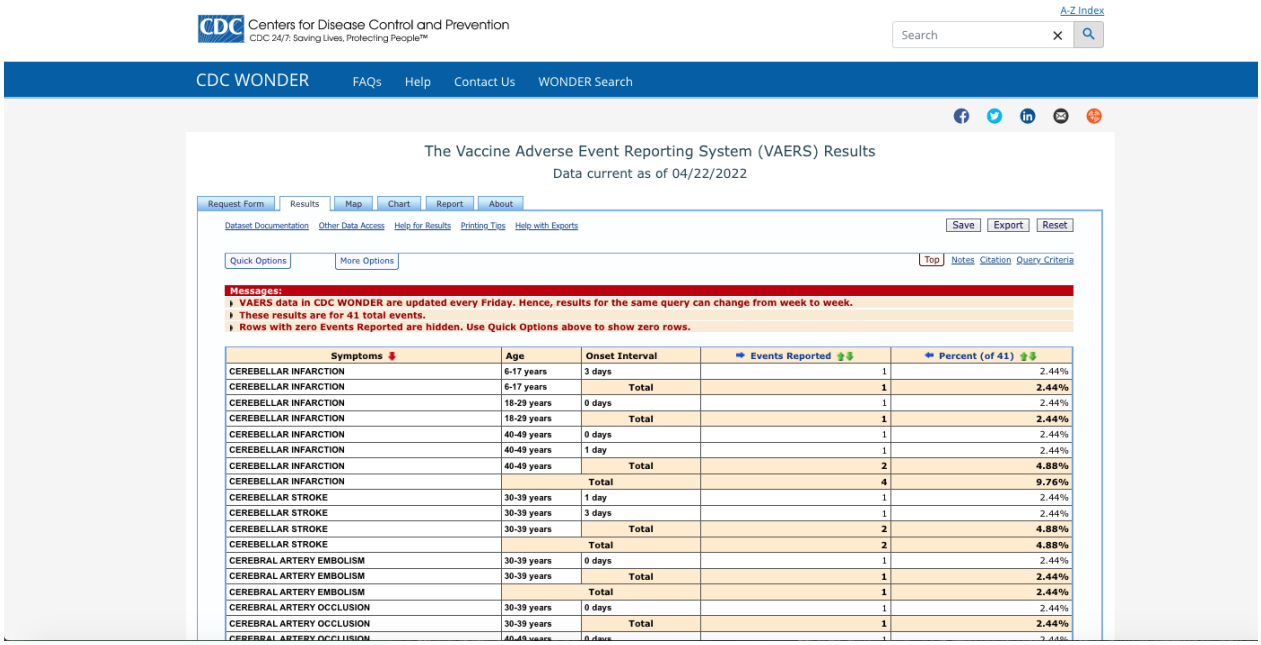
This next screenshot is the first page of a VAERS database search offering an overall look at those who received the Pfizer COVID vaccine and reported having a stroke during 2021 (all ages). It shows 561 strokes. Of these, 44 were reported in January and February of 2021 alone. [https://wonder.cdc.gov/controller/datarequest/D8]



A similar search for all Pfizer influenza vaccines (over 10 of them) for the years 2015 through 2019, showed not a single stroke was reported, as seen in the following screenshot. [https://wonder.cdc.gov/controller/datarequest/D8]



The next two screenshots are the results of a search on the VAERS database for the Pfizer vaccine only in conjunction with strokes within three days of receiving the vaccine during the time frame of December 2020 through 2021. The search resulted in 41 stroke incidences in people under the age of 50 [https://wonder.cdc.gov/controller/datarequest/D8]. According to the article from Socialstyrelsen, this is the age group with less than 4% of the strokes. [https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/statistik/2021-12-7644.pdf, p. 3] Most importantly, these 41 strokes occurred within three days of taking the vaccine, and about 44% occurred the very same day. This is highly suggestive of the vaccine being a strong contributing factor to, if not the cause of, the strokes. The search did not include the number of shots the person received, though many of the individual's reports did include this information. The number of shots varied from person to person. Some experienced a stroke after their second shot, but others experienced a stroke after just 1 shot. Most of the strokes were equally distributed between the 30-39 and the 40-49 age categories, but several were also seen in the 6-17 and the 18-29 age groups. In general, strokes in these age groups are rare.



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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The Vaccine Adverse Event Reporting System (VAERS) Results

Data current as of 04/22/2022

Request Form | Results | Map | Chart | Report | About

Dataset Documentation | Other Data Access | Help for Results | Printing Tips | Help with Exports | Save | Export | Reset

Quick Options | More Options | Top | Notes | Citation | Query Criteria

Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 41 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Symptoms	Age	Onset Interval	Events Reported	Percent (of 41)
CEREBELLAR INFARCTION	6-17 years	3 days	1	2.44%
CEREBELLAR INFARCTION	6-17 years	Total	1	2.44%
CEREBELLAR INFARCTION	18-29 years	0 days	1	2.44%
CEREBELLAR INFARCTION	18-29 years	Total	1	2.44%
CEREBELLAR INFARCTION	40-49 years	0 days	1	2.44%
CEREBELLAR INFARCTION	40-49 years	1 day	1	2.44%
CEREBELLAR INFARCTION	40-49 years	Total	2	4.88%
CEREBELLAR INFARCTION	Total		4	9.76%
CEREBELLAR STROKE	30-39 years	1 day	1	2.44%
CEREBELLAR STROKE	30-39 years	3 days	1	2.44%
CEREBELLAR STROKE	30-39 years	Total	2	4.88%
CEREBELLAR STROKE	Total		2	4.88%
CEREBRAL ARTERY EMBOLISM	30-39 years	0 days	1	2.44%
CEREBRAL ARTERY EMBOLISM	30-39 years	Total	1	2.44%
CEREBRAL ARTERY EMBOLISM	Total		1	2.44%
CEREBRAL ARTERY OCCLUSION	30-39 years	0 days	1	2.44%
CEREBRAL ARTERY OCCLUSION	30-39 years	Total	1	2.44%
CEREBRAL ARTERY OCCLUSION	40-49 years	0 days	1	2.44%
CEREBRAL THROMBOSIS	40-49 years	3 days	2	4.88%
CEREBRAL THROMBOSIS	40-49 years	Total	5	12.20%
CEREBRAL THROMBOSIS	Total		8	19.51%
CEREBRAL VENOUS SINUS THROMBOSIS	6-17 years	0 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	6-17 years	Total	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	18-29 years	0 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	18-29 years	2 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	18-29 years	3 days	2	4.88%
CEREBRAL VENOUS SINUS THROMBOSIS	18-29 years	Total	4	9.76%
CEREBRAL VENOUS SINUS THROMBOSIS	30-39 years	0 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	30-39 years	2 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	30-39 years	Total	2	4.88%
CEREBRAL VENOUS SINUS THROMBOSIS	40-49 years	0 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	40-49 years	1 day	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	40-49 years	Total	2	4.88%
CEREBRAL VENOUS SINUS THROMBOSIS	Total		9	21.95%
CEREBRAL VENOUS THROMBOSIS	40-49 years	0 days	1	2.44%
CEREBRAL VENOUS THROMBOSIS	40-49 years	Total	1	2.44%
CEREBRAL VENOUS THROMBOSIS	Total		1	2.44%
Total			46	112.20%

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Top | Options | Notes | Citation | Query Criteria

Notes:

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

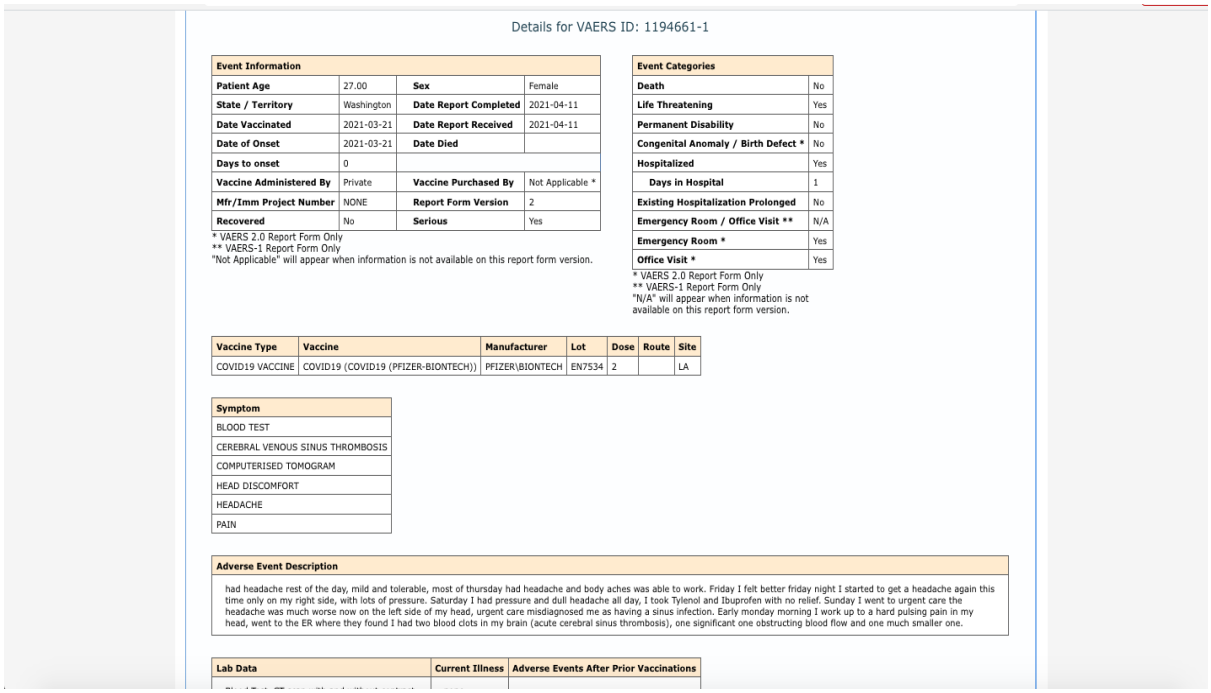
The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity,

Taking a closer look at the individuals who suffered these strokes shows that many of these people were young and healthy without much medical history. The following screenshots are a few examples. [https://wonder.cdc.gov/controller/datarequest/D8]

This screenshot details two cerebral venous sinus thrombi detected in a 27-year-old female that received the second dose of a Pfizer COVID-19 vaccine. The onset of her symptoms started the same day she received the injection. [https://wonder.cdc.gov/controller/datarequest/D8]



Details for VAERS ID: 1194661-1

Event Information			
Patient Age	27.00	**Sex**	Female
State / Territory	Washington	**Date Report Completed**	2021-04-11
Date Vaccinated	2021-03-21	**Date Report Received**	2021-04-11
Date of Onset	2021-03-21	**Date Died**	
Days to onset	0		
Vaccine Administered By	Private	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	Yes
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	1
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

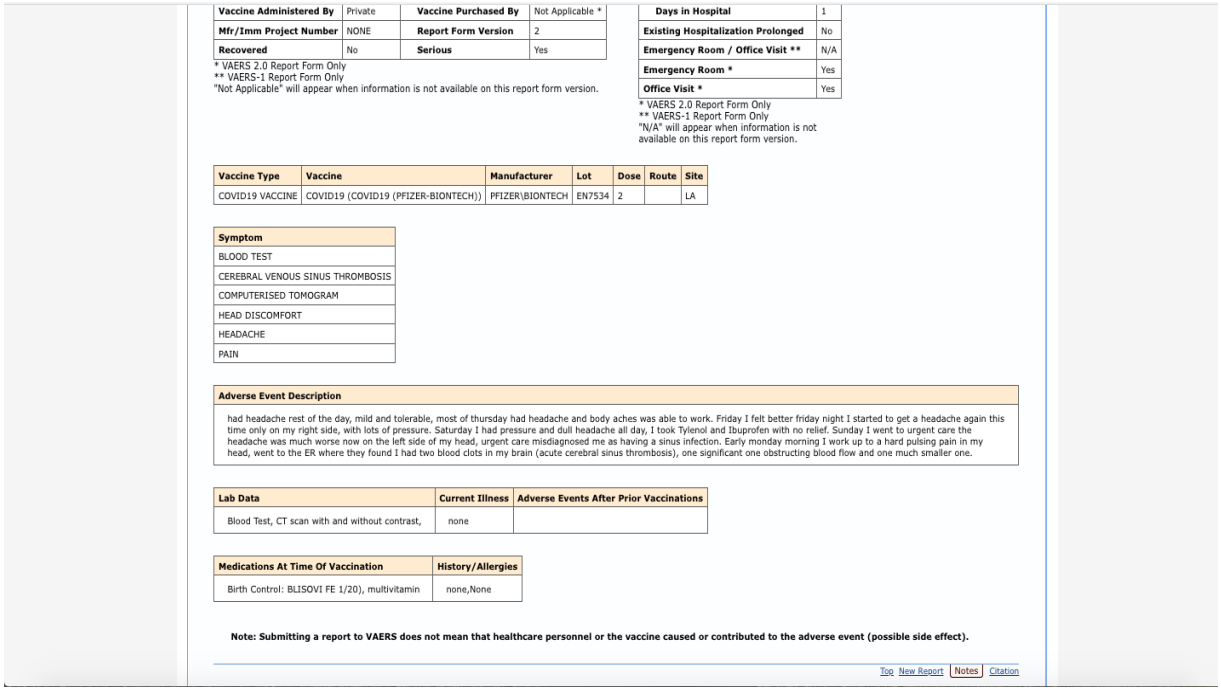
Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EN7534	2		LA

Symptom
BLOOD TEST
CEREBRAL VENOUS SINUS THROMBOSIS
COMPUTERISED TOMOGRAM
HEAD DISCOMFORT
HEADACHE
PAIN

Adverse Event Description

had headache rest of the day, mild and tolerable, most of thursday had headache and body aches was able to work. Friday I felt better friday night I started to get a headache again this time only on my right side, with lots of pressure. Saturday I had pressure and dull headache all day, I took Tylenol and Ibuprofen with no relief. Sunday I went to urgent care the headache was much worse now on the left side of my head, urgent care misdiagnosed me as having a sinus infection. Early monday morning I work up to a hard pulsing pain in my head, went to the ER where they found I had two blood clots in my brain (acute cerebral sinus thrombosis), one significant one obstructing blood flow and one much smaller one.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations



Vaccine Administered By	Private	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Days in Hospital	1
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EN7534	2		LA

Symptom
BLOOD TEST
CEREBRAL VENOUS SINUS THROMBOSIS
COMPUTERISED TOMOGRAM
HEAD DISCOMFORT
HEADACHE
PAIN

Adverse Event Description

had headache rest of the day, mild and tolerable, most of thursday had headache and body aches was able to work. Friday I felt better friday night I started to get a headache again this time only on my right side, with lots of pressure. Saturday I had pressure and dull headache all day, I took Tylenol and Ibuprofen with no relief. Sunday I went to urgent care the headache was much worse now on the left side of my head, urgent care misdiagnosed me as having a sinus infection. Early monday morning I work up to a hard pulsing pain in my head, went to the ER where they found I had two blood clots in my brain (acute cerebral sinus thrombosis), one significant one obstructing blood flow and one much smaller one.

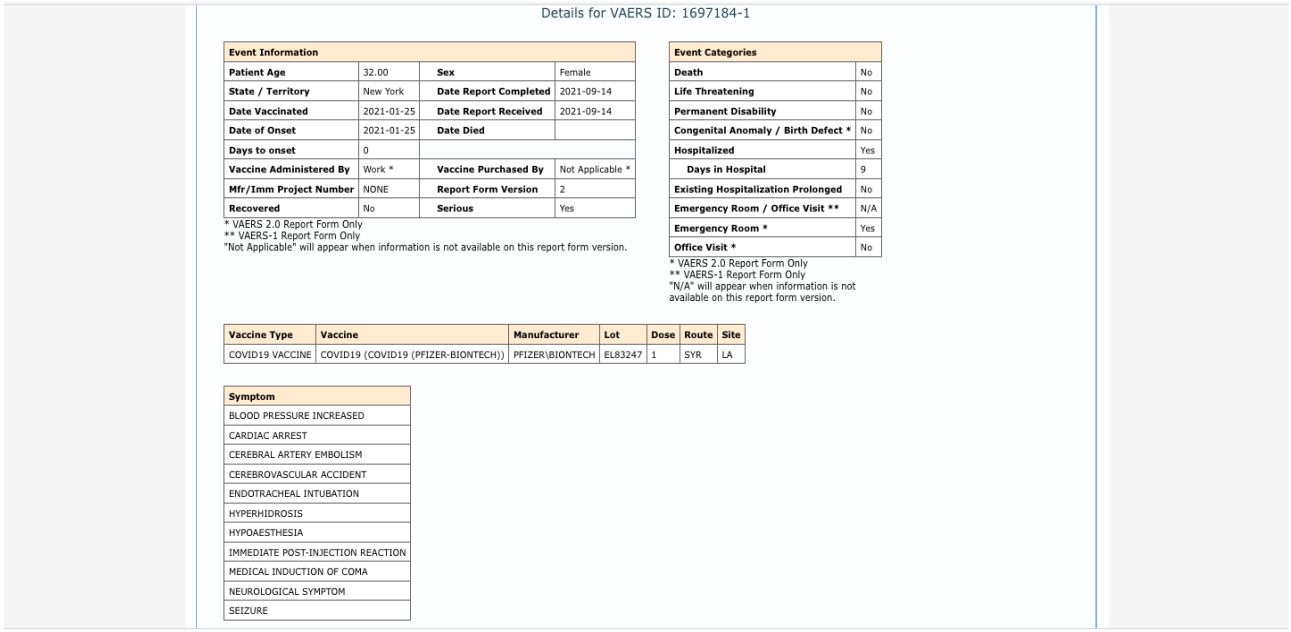
Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Blood Test, CT scan with and without contrast,	none	

Medications At Time Of Vaccination	History/Allergies
Birth Control: BLISOVI FE 1/20), multivitamin	none,None

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Top New Report Notes Citation

The next two screenshots show a 32-year-old healthy woman, with no prior medical history other than some allergies, having an immediate reaction to the first dose of vaccine. She had a stroke and was put into a medical coma, during which she coded and had seizures. She had to be intubated and ventilated but, fortunately, recovered enough to be released from the hospital eight days later. [https://wonder.cdc.gov/controller/datarequest/D8]



Details for VAERS ID: 1697184-1

Event Information			
Patient Age	32.00	**Sex**	Female
State / Territory	New York	**Date Report Completed**	2021-09-14
Date Vaccinated	2021-01-25	**Date Report Received**	2021-09-14
Date of Onset	2021-01-25	**Date Died**	
Days to onset	0		
Vaccine Administered By	Work *	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

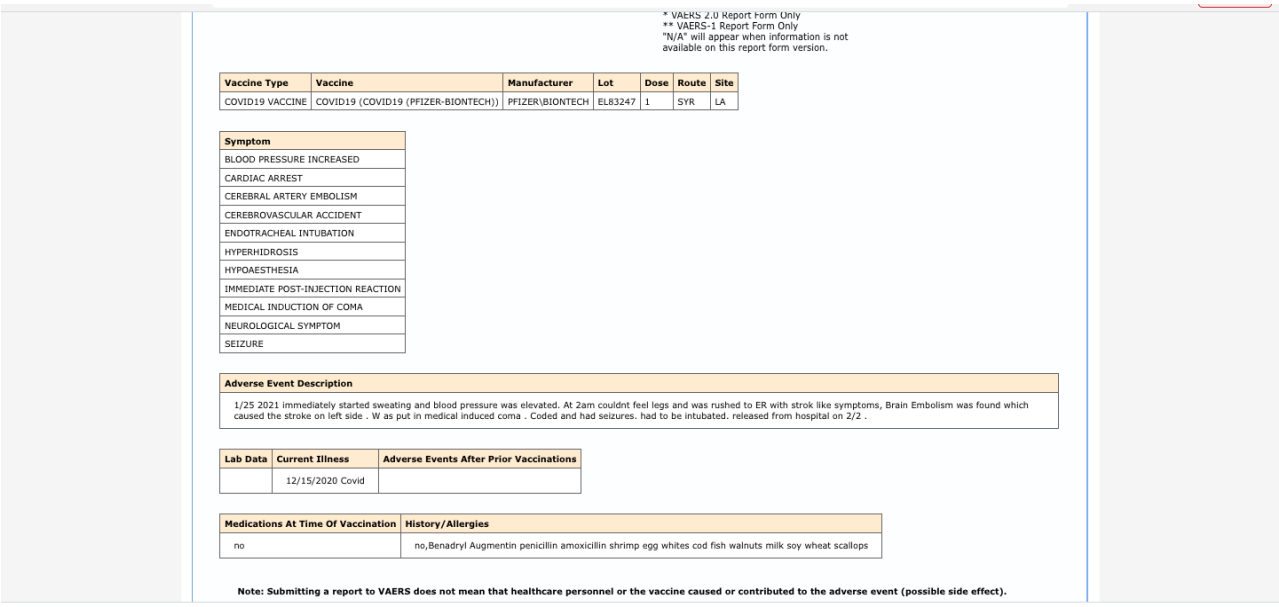
* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	9
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EL83247	1	SYR	LA

Symptom
BLOOD PRESSURE INCREASED
CARDIAC ARREST
CEREBRAL ARTERY EMBOLISM
CEREBROVASCULAR ACCIDENT
ENDOTRACHEAL INTUBATION
HYPERHIDROSIS
HYPOAESTHESIA
IMMEDIATE POST-INJECTION REACTION
MEDICAL INDUCTION OF COMA
NEUROLOGICAL SYMPTOM
SEIZURE



* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EL83247	1	SYR	LA

Symptom
BLOOD PRESSURE INCREASED
CARDIAC ARREST
CEREBRAL ARTERY EMBOLISM
CEREBROVASCULAR ACCIDENT
ENDOTRACHEAL INTUBATION
HYPERHIDROSIS
HYPOAESTHESIA
IMMEDIATE POST-INJECTION REACTION
MEDICAL INDUCTION OF COMA
NEUROLOGICAL SYMPTOM
SEIZURE

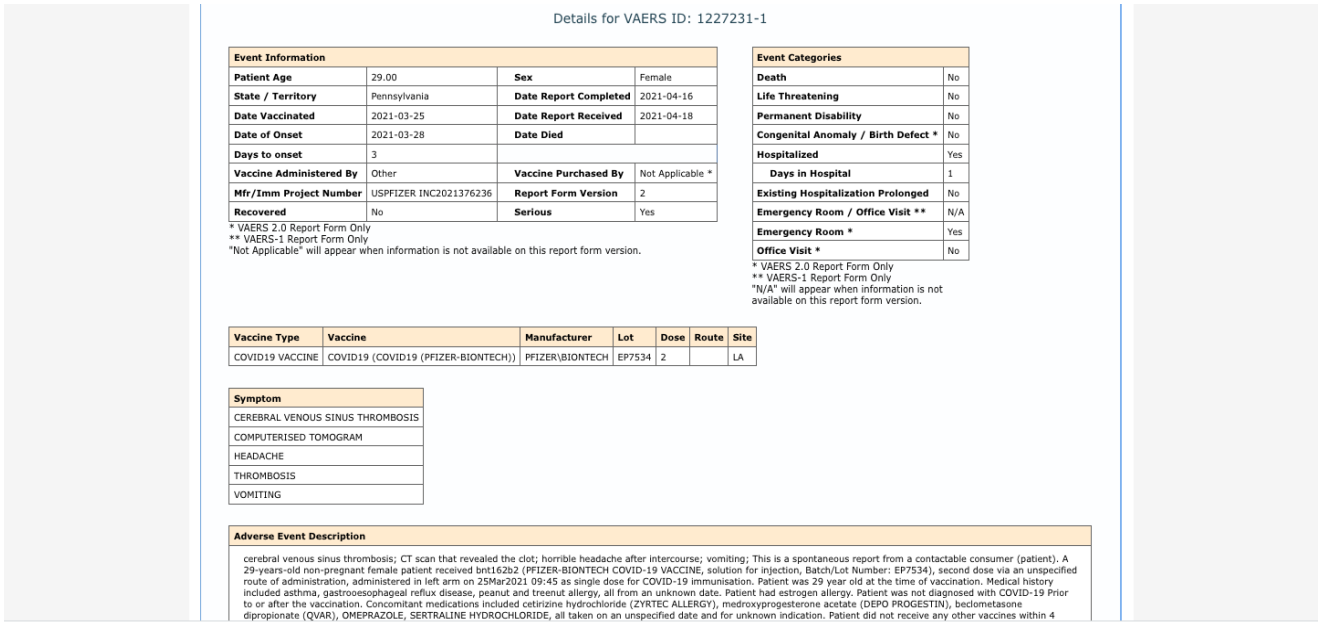
Adverse Event Description
1/25 2021 immediately started sweating and blood pressure was elevated. At 2am couldnt feel legs and was rushed to ER with strok like symptoms, Brain Embolism was found which caused the stroke on left side . W as put in medical induced coma . Coded and had seizures. had to be intubated. released from hospital on 2/2 .

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
	12/15/2020 Covid	

Medications At Time Of Vaccination	History/Allergies
no	no,Benadryl Augmentin penicillin amoxicillin shrimp egg whites cod fish walnuts milk soy wheat scallops

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

The next two screenshots are from a 29-year-old female that suffered a severe headache and vomiting due to a cerebral venous sinus thrombosis after her second dose. Her medical history included asthma and GERD (Gastroesophageal Reflux Disease) and a few allergies, none of which would make her at risk for a stroke. [https://wonder.cdc.gov/controller/datarequest/D8]



Details for VAERS ID: 1227231-1

Event Information			
Patient Age	29.00	**Sex**	Female
State / Territory	Pennsylvania	**Date Report Completed**	2021-04-16
Date Vaccinated	2021-03-25	**Date Report Received**	2021-04-18
Date of Onset	2021-03-28	**Date Died**	
Days to onset	3		
Vaccine Administered By	Other	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	USPFIZER INC2021376236	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	1
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

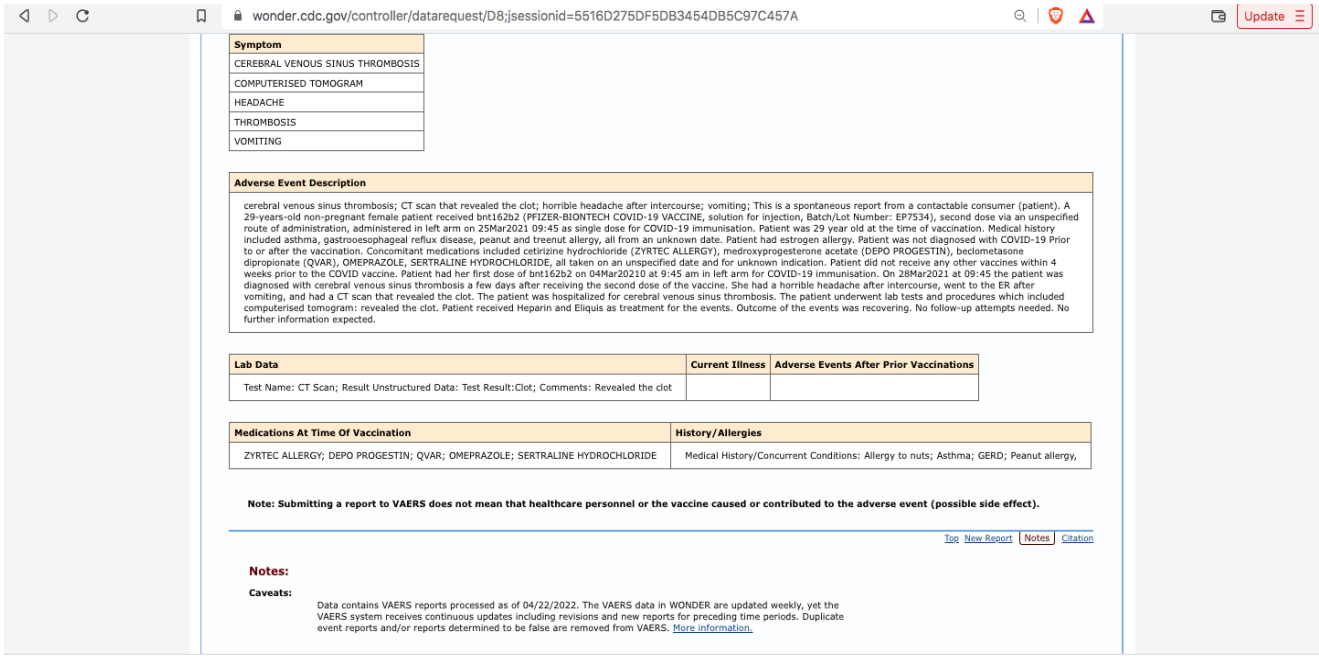
* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	EP7534	2		LA

Symptom
CEREBRAL VENOUS SINUS THROMBOSIS
COMPUTERISED TOMOGRAM
HEADACHE
THROMBOSIS
VOMITING

Adverse Event Description

cerebral venous sinus thrombosis; CT scan that revealed the clot; horrible headache after intercourse; vomiting; This is a spontaneous report from a contactable consumer (patient). A 29-years-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EP7534), second dose via an unspecified route of administration, administered in left arm on 25Mar2021 09:45 as single dose for COVID-19 immunisation. Patient was 29 year old at the time of vaccination. Medical history included asthma, gastrooesophageal reflux disease, peanut and treenut allergy, all from an unknown date. Patient had estrogen allergy. Patient was not diagnosed with COVID-19 Prior to or after the vaccination. Concomitant medications included cetirizine hydrochloride (ZYRTEC ALLERGY), medroxyprogesterone acetate (DEPO PROGESTIN), beclometasone dipropionate (QVAR), OMEPRAZOLE, SERTRALINE HYDROCHLORIDE, all taken on an unspecified date and for unknown indication. Patient did not receive any other vaccines within 4



wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Update

Symptom
CEREBRAL VENOUS SINUS THROMBOSIS
COMPUTERISED TOMOGRAM
HEADACHE
THROMBOSIS
VOMITING

Adverse Event Description

cerebral venous sinus thrombosis; CT scan that revealed the clot; horrible headache after intercourse; vomiting; This is a spontaneous report from a contactable consumer (patient). A 29-years-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EP7534), second dose via an unspecified route of administration, administered in left arm on 25Mar2021 09:45 as single dose for COVID-19 immunisation. Patient was 29 year old at the time of vaccination. Medical history included asthma, gastrooesophageal reflux disease, peanut and treenut allergy, all from an unknown date. Patient had estrogen allergy. Patient was not diagnosed with COVID-19 Prior to or after the vaccination. Concomitant medications included cetirizine hydrochloride (ZYRTEC ALLERGY), medroxyprogesterone acetate (DEPO PROGESTIN), beclometasone dipropionate (QVAR), OMEPRAZOLE, SERTRALINE HYDROCHLORIDE, all taken on an unspecified date and for unknown indication. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient had her first dose of bnt162b2 on 04Mar20210 at 9:45 am in left arm for COVID-19 immunisation. On 28Mar2021 at 09:45 the patient was diagnosed with cerebral venous sinus thrombosis a few days after receiving the second dose of the vaccine. She had a horrible headache after intercourse, went to the ER after vomiting, and had a CT scan that revealed the clot. The patient was hospitalized for cerebral venous sinus thrombosis. The patient underwent lab tests and procedures which included computerised tomogram: revealed the clot. Patient received Heparin and Eliquis as treatment for the events. Outcome of the events was recovering. No follow-up attempts needed. No further information expected.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Name: CT Scan; Result Unstructured Data: Test Result:Clot; Comments: Revealed the clot		

Medications At Time Of Vaccination	History/Allergies
ZYRTEC ALLERGY; DEPO PROGESTIN; QVAR; OMEPRAZOLE; SERTRALINE HYDROCHLORIDE	Medical History/Concurrent Conditions: Allergy to nuts; Asthma; GERD; Peanut allergy,

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

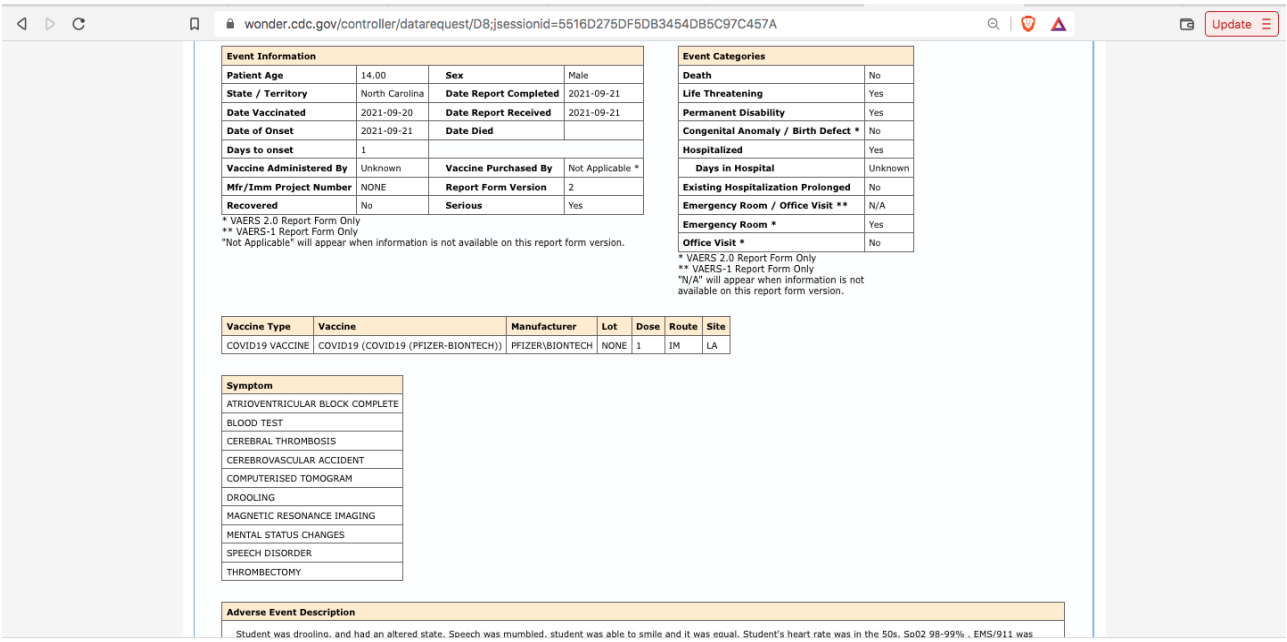
Top New Report Notes Citation

Notes:

Caveats:

Data contains VAERS reports processed as of 04/22/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information.

This next example is a 14-year-old healthy male with no medical history. One day after one dose of vaccination, he suffered a cerebral thrombosis and a third-degree heart block. He was left permanently disabled. [https://wonder.cdc.gov/controller/datarequest/D8]



wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Update

Event Information			
Patient Age	14.00	Sex	Male
State / Territory	North Carolina	Date Report Completed	2021-09-21
Date Vaccinated	2021-09-20	Date Report Received	2021-09-21
Date of Onset	2021-09-21	Date Died	
Days to onset	1		
Vaccine Administered By	Unknown	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	Yes
Permanent Disability	Yes
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	Unknown
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

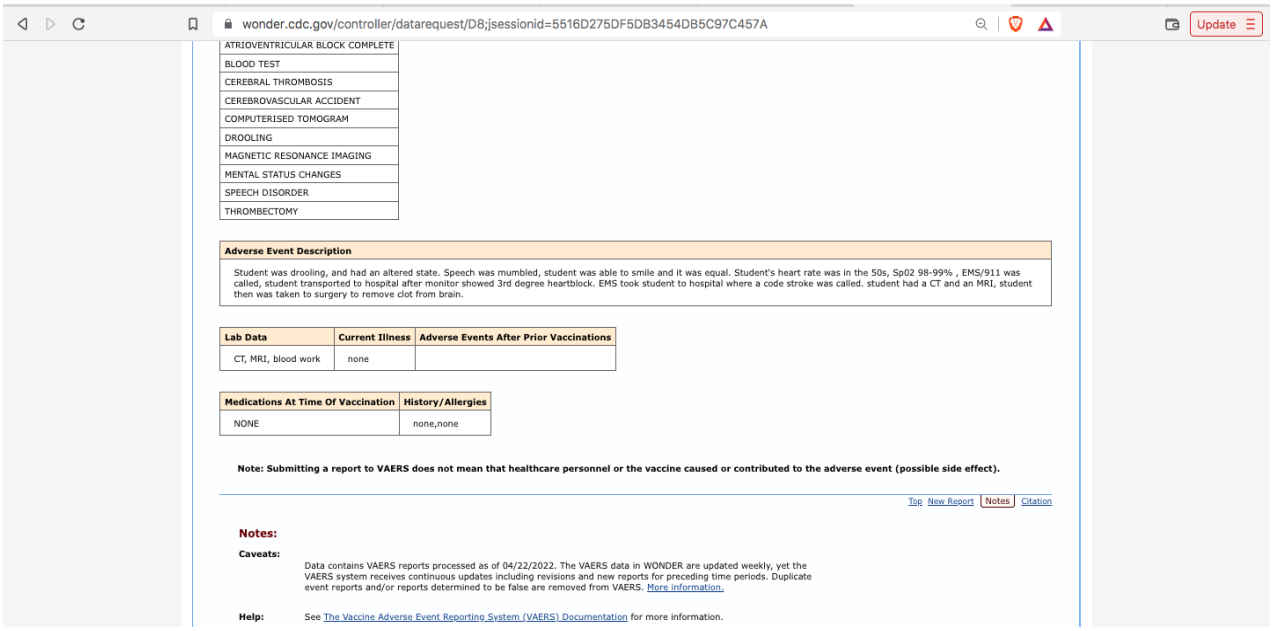
* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	NONE	1	IM	LA

Symptom
ATRIOVENTRICULAR BLOCK COMPLETE
BLOOD TEST
CEREBRAL THROMBOSIS
CEREBROVASCULAR ACCIDENT
COMPUTERISED TOMOGRAM
DROOLING
MAGNETIC RESONANCE IMAGING
MENTAL STATUS CHANGES
SPEECH DISORDER
THROMBECTOMY

Adverse Event Description

Student was drooling, and had an altered state. Speech was mumbled, student was able to smile and it was equal. Student's heart rate was in the 50s, Sp02 98-99% , EMS/911 was



wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Update

Symptom
ATRIOVENTRICULAR BLOCK COMPLETE
BLOOD TEST
CEREBRAL THROMBOSIS
CEREBROVASCULAR ACCIDENT
COMPUTERISED TOMOGRAM
DROOLING
MAGNETIC RESONANCE IMAGING
MENTAL STATUS CHANGES
SPEECH DISORDER
THROMBECTOMY

Adverse Event Description

Student was drooling, and had an altered state. Speech was mumbled, student was able to smile and it was equal. Student's heart rate was in the 50s, Sp02 98-99% , EMS/911 was called, student transported to hospital after monitor showed 3rd degree heartblock. EMS took student to hospital where a code stroke was called. student had a CT and an MRI, student then was taken to surgery to remove clot from brain.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
CT, MRI, blood work	none	

Medications At Time Of Vaccination	History/Allergies
NONE	none,none

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

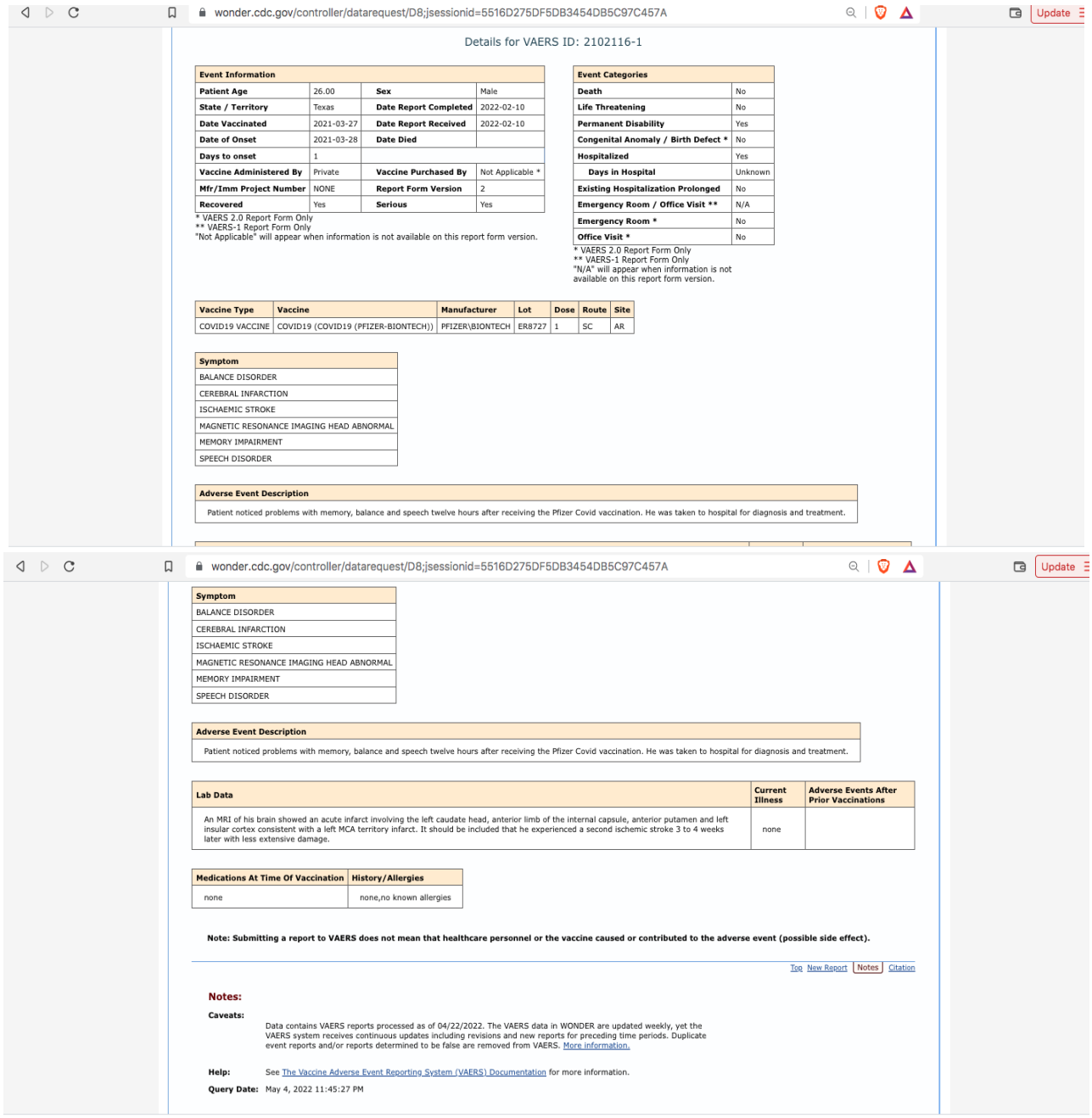
Top New Report Notes Citation

Notes:

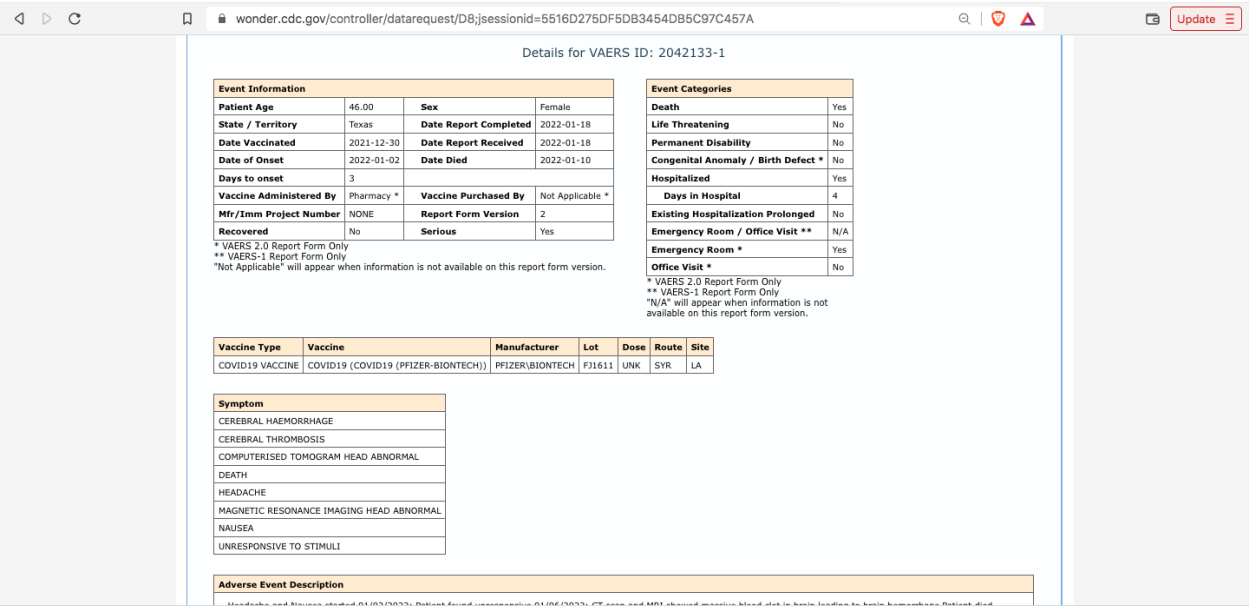
Caveats: Data contains VAERS reports processed as of 04/22/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information.

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation for more information.

A previously healthy 26-year-old male with no medical history is now permanently disabled. He noticed memory, balance and speech problems just 12 hours after receiving his first dose of the Pfizer vaccine. He was diagnosed with an acute infarct involving the left caudate head, anterior limb of the internal capsule, anterior putamen and left insular cortex. He also suffered a second ischemic stroke three to four weeks later. [https://wonder.cdc.gov/controller/datarequest/D8]



A 46-year-old female experienced headache and nausea starting just 3 days post vaccination. Four days later she was found unresponsive. CT and MRI scans showed massive blood clot in the brain with hemorrhage. She died 11 days after vaccination. Her report indicates no medical history or co-morbidities. [https://wonder.cdc.gov/controller/datarequest/D8]



wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Update

Details for VAERS ID: 2042133-1

Event Information			
Patient Age	46.00	**Sex**	Female
State / Territory	Texas	**Date Report Completed**	2022-01-18
Date Vaccinated	2021-12-30	**Date Report Received**	2022-01-18
Date of Onset	2022-01-02	**Date Died**	2022-01-10
Days to onset	3		
Vaccine Administered By	Pharmacy *	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

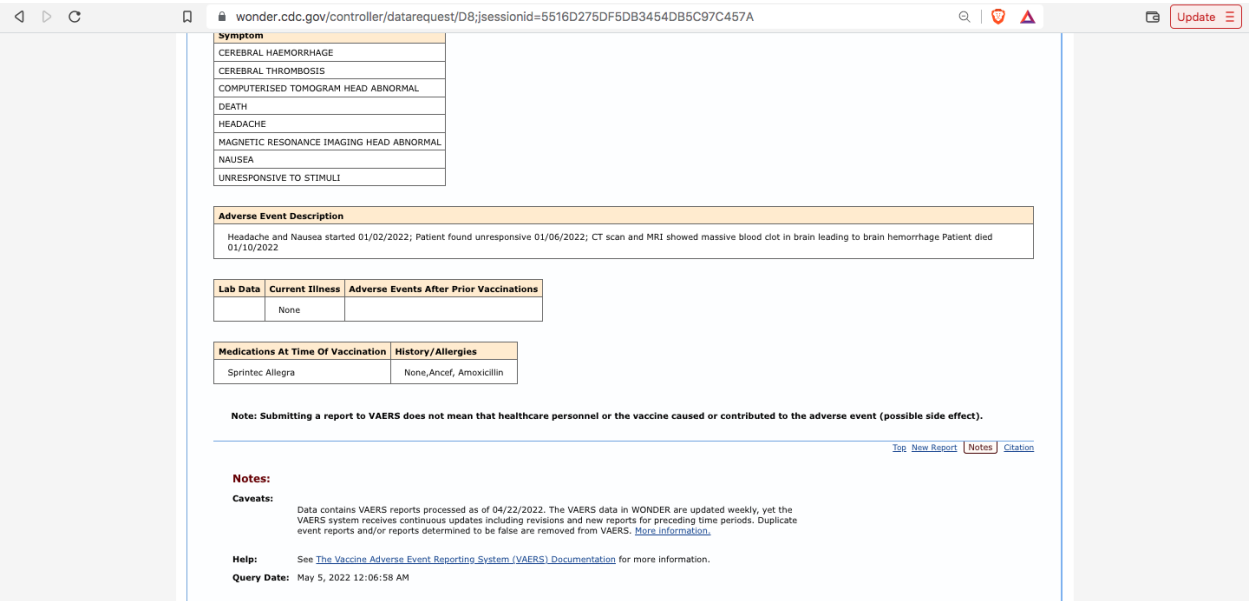
Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	4
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	FJ1611	UNK	SYR	LA

Symptom
CEREBRAL HAEMORRHAGE
CEREBRAL THROMBOSIS
COMPUTERISED TOMOGRAM HEAD ABNORMAL
DEATH
HEADACHE
MAGNETIC RESONANCE IMAGING HEAD ABNORMAL
NAUSEA
UNRESPONSIVE TO STIMULI

Adverse Event Description



wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Update

Symptom
CEREBRAL HAEMORRHAGE
CEREBRAL THROMBOSIS
COMPUTERISED TOMOGRAM HEAD ABNORMAL
DEATH
HEADACHE
MAGNETIC RESONANCE IMAGING HEAD ABNORMAL
NAUSEA
UNRESPONSIVE TO STIMULI

Adverse Event Description

Headache and Nausea started 01/02/2022; Patient found unresponsive 01/06/2022; CT scan and MRI showed massive blood clot in brain leading to brain hemorrhage Patient died 01/10/2022

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
	None	

Medications At Time Of Vaccination	History/Allergies
Sprintec Allegra	None,Ancef, Amoxicillin

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Top New Report Notes Citation

Notes:

Caveats: Data contains VAERS reports processed as of 04/22/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information.

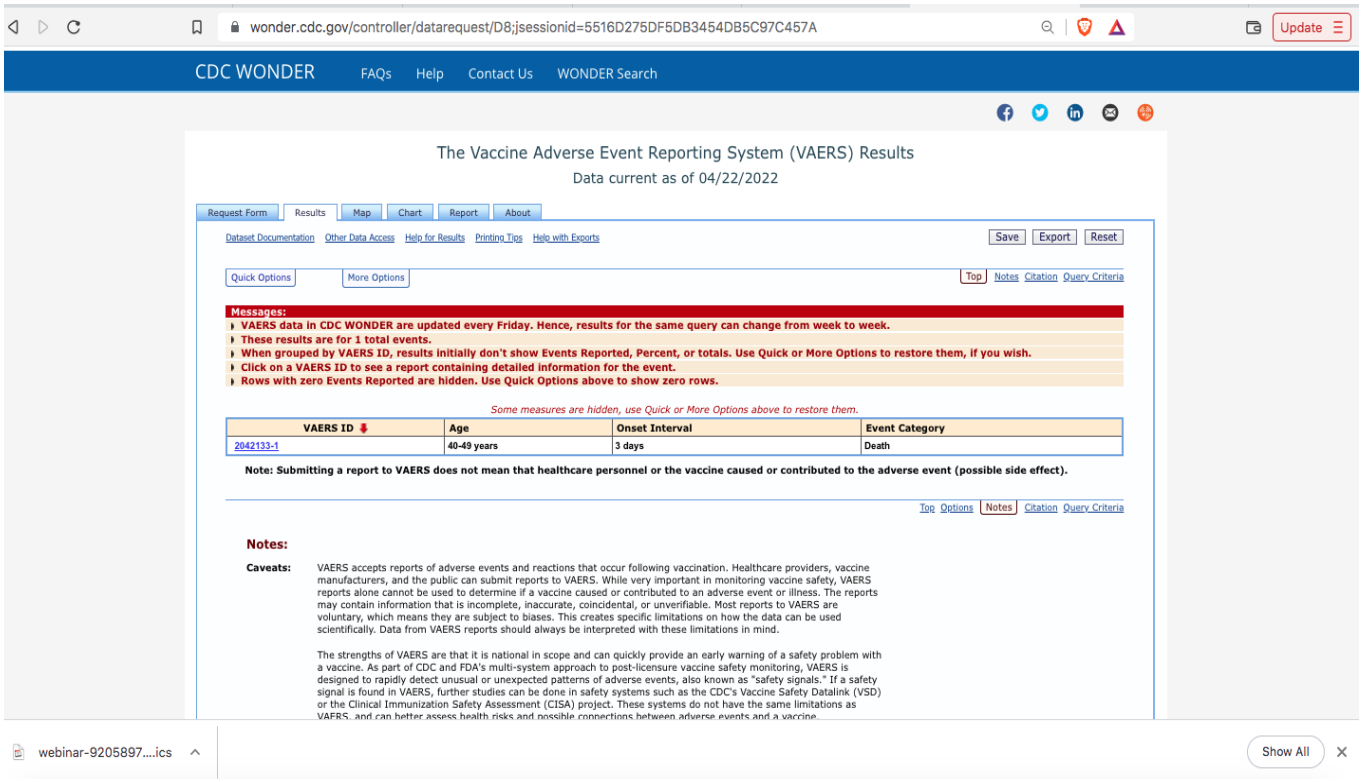
Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation for more information.

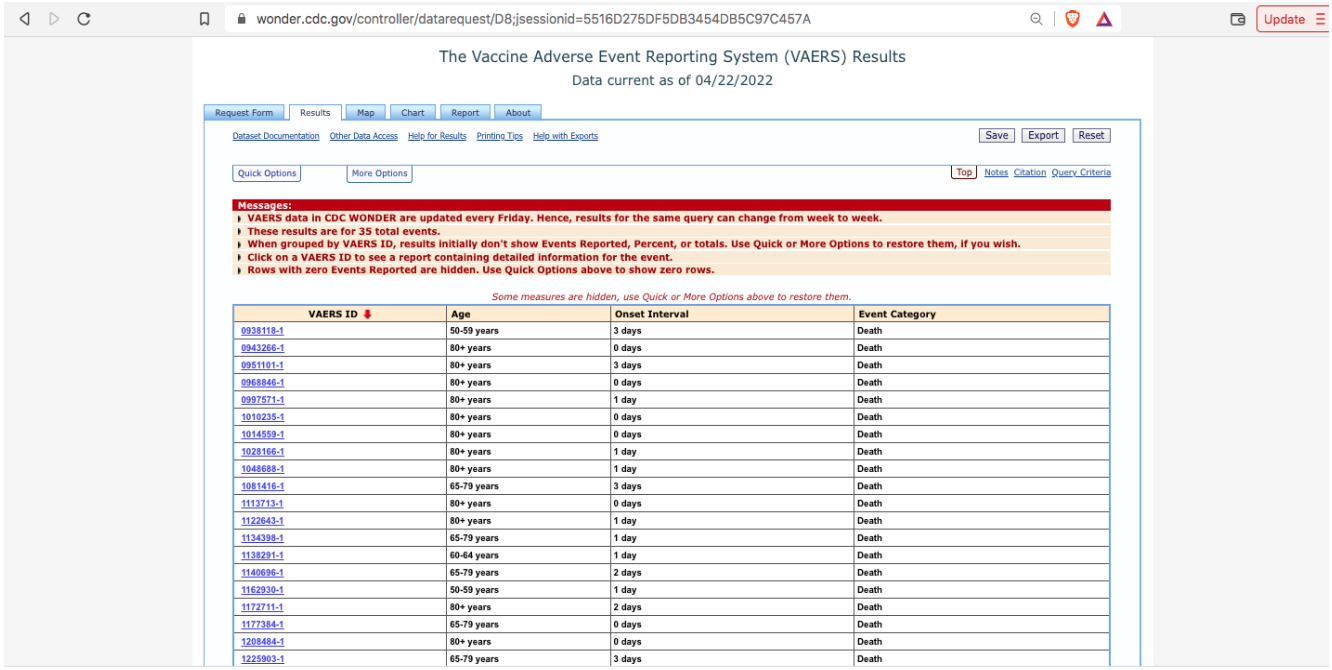
Query Date: May 5, 2022 12:06:58 AM

It is known that adverse reactions to vaccinations are under-reported in the VAERS database. It normally only reflects a small fraction of the adverse event occurrences.[https://vaers.hhs.gov/data/dataguide.html] So, if this is true, it is more likely that 410 to 4100 strokes have occurred in the United States alone within three days of Pfizer vaccination in people under 50 years of age. Bear in mind that this age group normally reflects only four percent of the incidences of stroke overall. VAERS also states that just because an event is recorded it may not be caused by the vaccine [https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Understanding-the-Vaccine-Adverse-Event-Reporting-System-(VAERS).pdf], which could very well be true for some. But the sheer number of these adverse events compared to adverse events for other vaccinations, the

ages and health status of the victims, and the timing of the adverse events relative to COVID vaccination are all indicative of the COVID vaccine being the cause.

The next several screenshots are of the VAERS database searches for death or permanent disability due to strokes within three days of Pfizer vaccination for a 13-month period. [https://wonder.cdc.gov/controller/datarequest/D8] One death was reported in the under-50 age category, and 35 deaths reported in the 50-and-over age range. Seventeen people under 50 have been permanently disabled, and 51 people in the 50-or-above age range are permanently disabled all within three days post-Pfizer COVID-19 vaccination. [https://wonder.cdc.gov/controller/datarequest/D8]





The Vaccine Adverse Event Reporting System (VAERS) Results

Data current as of 04/22/2022

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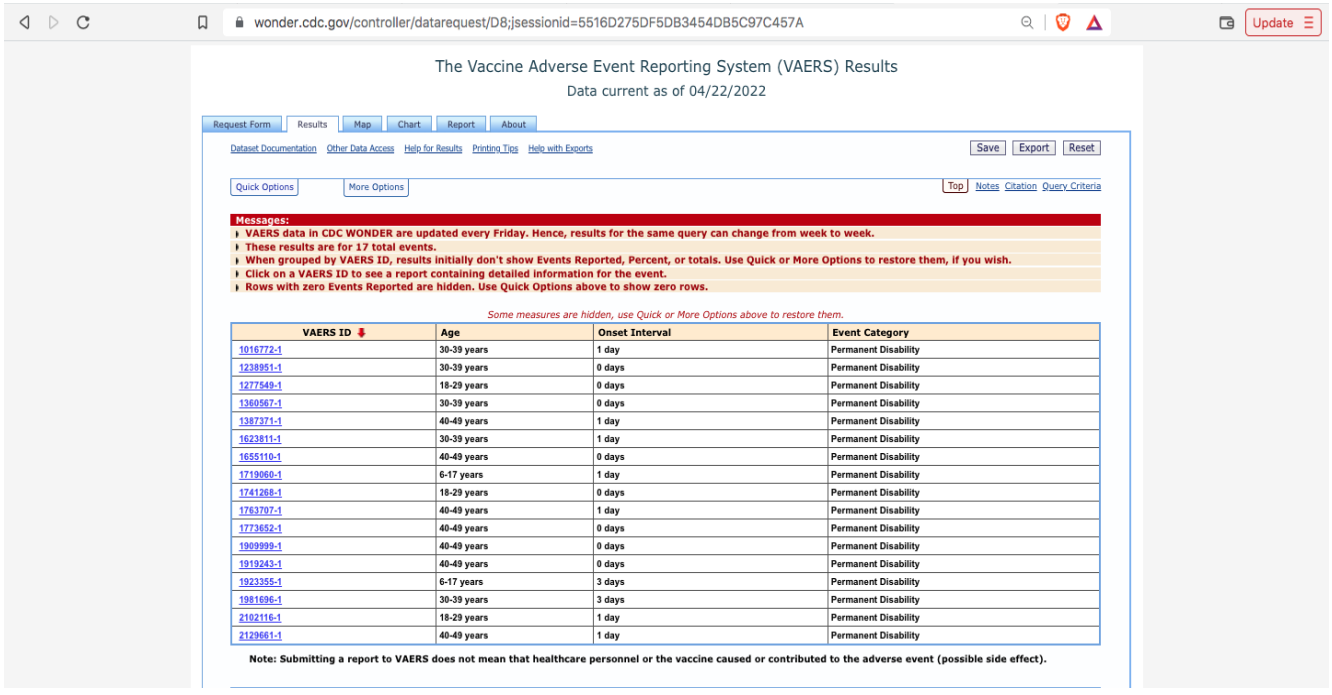
Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 35 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Some measures are hidden, use Quick or More Options above to restore them.

VAERS ID	Age	Onset Interval	Event Category
0938118-1	50-59 years	3 days	Death
0943266-1	80+ years	0 days	Death
0951101-1	80+ years	3 days	Death
0968846-1	80+ years	0 days	Death
0997571-1	80+ years	1 day	Death
1010235-1	80+ years	0 days	Death
1014559-1	80+ years	0 days	Death
1028166-1	80+ years	1 day	Death
1048688-1	80+ years	1 day	Death
1081416-1	65-79 years	3 days	Death
1113713-1	80+ years	0 days	Death
1122643-1	80+ years	1 day	Death
1134398-1	65-79 years	1 day	Death
1138291-1	60-64 years	1 day	Death
1140696-1	65-79 years	2 days	Death
1162930-1	50-59 years	1 day	Death
1172711-1	80+ years	2 days	Death
1177384-1	65-79 years	0 days	Death
1208484-1	80+ years	0 days	Death
1225903-1	65-79 years	3 days	Death



The Vaccine Adverse Event Reporting System (VAERS) Results

Data current as of 04/22/2022

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Top | Notes | Citation | Query Criteria

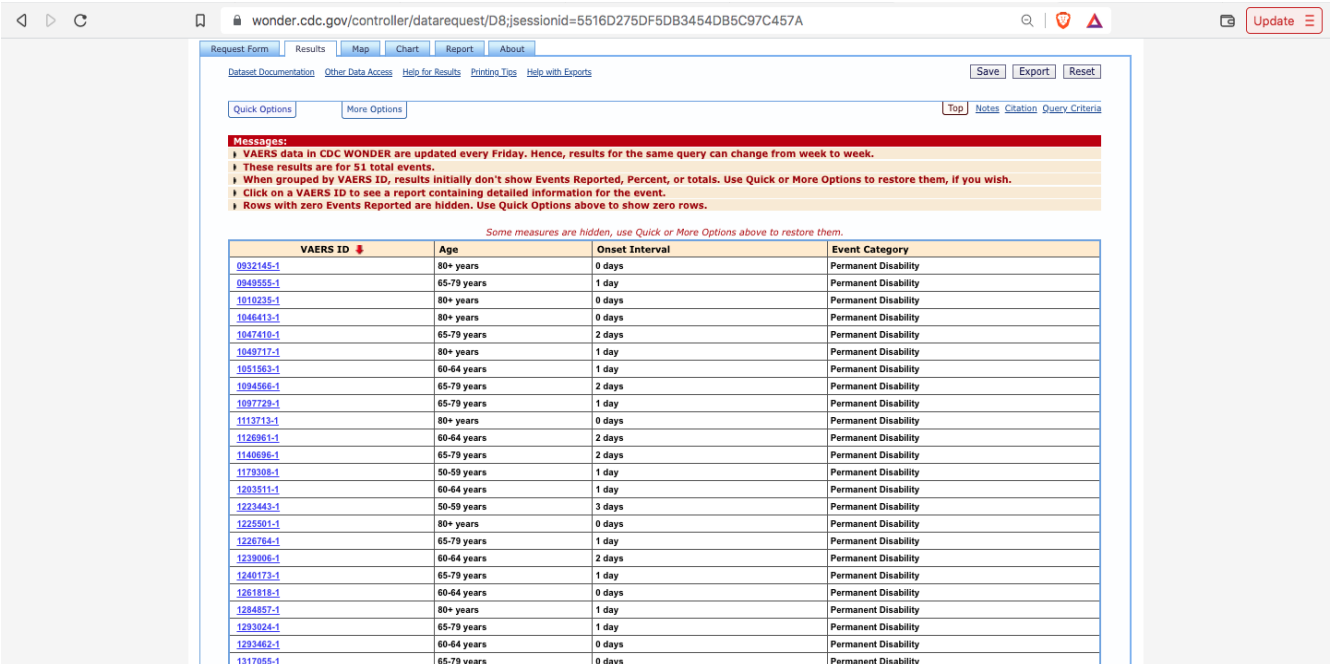
Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 17 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Some measures are hidden, use Quick or More Options above to restore them.

VAERS ID	Age	Onset Interval	Event Category
1016772-1	30-39 years	1 day	Permanent Disability
1238951-1	30-39 years	0 days	Permanent Disability
1277549-1	18-29 years	0 days	Permanent Disability
1360567-1	30-39 years	0 days	Permanent Disability
1387371-1	40-49 years	1 day	Permanent Disability
1623811-1	30-39 years	1 day	Permanent Disability
1655110-1	40-49 years	0 days	Permanent Disability
1719060-1	6-17 years	1 day	Permanent Disability
1741268-1	18-29 years	0 days	Permanent Disability
1763707-1	40-49 years	1 day	Permanent Disability
1773652-1	40-49 years	0 days	Permanent Disability
1909999-1	40-49 years	0 days	Permanent Disability
1919243-1	40-49 years	0 days	Permanent Disability
1923355-1	6-17 years	3 days	Permanent Disability
1981696-1	30-39 years	3 days	Permanent Disability
2102116-1	18-29 years	1 day	Permanent Disability
2129661-1	40-49 years	1 day	Permanent Disability

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).



wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Request Form | Results | Map | Chart | Report | About

Dataset Documentation | Other Data Access | Help for Results | Printing Tips | Help with Exports

Save | Export | Reset

Quick Options | More Options

Top | Notes | Citation | Query Criteria

Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 51 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Some measures are hidden, use Quick or More Options above to restore them.

VAERS ID	Age	Onset Interval	Event Category
0932145-1	80+ years	0 days	Permanent Disability
0949555-1	65-79 years	1 day	Permanent Disability
1010235-1	80+ years	0 days	Permanent Disability
1046413-1	80+ years	0 days	Permanent Disability
1047410-1	65-79 years	2 days	Permanent Disability
1049717-1	80+ years	1 day	Permanent Disability
1051563-1	60-64 years	1 day	Permanent Disability
1094566-1	65-79 years	2 days	Permanent Disability
1097729-1	65-79 years	1 day	Permanent Disability
1113713-1	80+ years	0 days	Permanent Disability
1126961-1	60-64 years	2 days	Permanent Disability
1140696-1	65-79 years	2 days	Permanent Disability
1179308-1	50-59 years	1 day	Permanent Disability
1203511-1	60-64 years	1 day	Permanent Disability
1223443-1	50-59 years	3 days	Permanent Disability
1225501-1	80+ years	0 days	Permanent Disability
1226764-1	65-79 years	1 day	Permanent Disability
1239006-1	60-64 years	2 days	Permanent Disability
1240173-1	65-79 years	1 day	Permanent Disability
1261818-1	60-64 years	0 days	Permanent Disability
1284857-1	80+ years	1 day	Permanent Disability
1293024-1	65-79 years	1 day	Permanent Disability
1293462-1	60-64 years	0 days	Permanent Disability
1317055-1	65-79 years	0 days	Permanent Disability

In conclusion, the number of stroke reports for the Pfizer vaccine in its first year was 561 for all ages compared to zero strokes reported for over 10 different Pfizer influenza vaccines over a four-year period. This alone is a reason for concern. Taking a closer look at the timing of the strokes in relation to vaccination in previously healthy people adds even more credence that the Pfizer COVID vaccine is unsafe. Keep in mind that many of these people were also in an age group in which strokes are generally not prevalent. Stroke is just one of the many adverse events reported in the VAERS database for the Pfizer vaccine. These reports were occurring as early as January 2021; and the CDC, FDA, and Pfizer did not pause in pushing for mass vaccination of the unsuspecting and trusting public, resulting in deaths and permanent disabilities.

Report 23: "Proof the TrialMax App Unequivocally Contributed to Pfizer's Deception of Safety" by Camille Villa – Team 1.

In the latest batch of the court-ordered release of Pfizer documents, there is unbelievable evidence supporting THE BIG LIE - that Pfizer's vaccine was safe. In a document titled, "Annotated Study Book for Study Design," we discover Pfizer contracted with a company called Signant Health to create an app in which trial participants could enter all their side effects. https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sample-crf.pdf The app, called TrialMax, was used to collect patient data in phase one and phase two of Pfizer's COVID vaccine clinical trials (the C4591001-Post-12-July-2020 study). Pfizer required all participants to log their side effects daily, however, this app was intentionally created to exclude nearly all adverse events!

According to Signant Health, the user-friendly healthcare app developer, the goal of this app was to collect and manage a high volume of data from Pfizer's "reactogenicity and COVID-19 illness diaries' ' in an effort to gain approval of the emergency use authorization. https://www.signanthealth.com/wp-content/uploads/2021/09/Case-Study-Coronavirus-Vaccines.pdf A considerable failure of the app, however, was that it purposefully limited a trial participant's input to only specific predetermined side effects.

Pfizer's deception of safety was further supported by the basic philosophy of the TrialMax app developer. In a 2019 Clinical Research News article, discussing the company's focus on simplified solutions, Signant Health's CEO states, ". . . the more difficult it is to participate—the more impactful it is on somebody's life, the more complex the technology or the process is—the less likely somebody is going to stay in a trial." https://www.clinicalresearchnewsonline.com/news/2019/06/10/crf-bracket-relaunches-as-signant-health The article goes on to state that Signant Health's objective is "to make it easier to participate in—and run—clinical trials." In a supposed effort to keep the participants' engagement uncomplicated, we can deduce that Pfizer purposefully substituted simplicity for safety by directing Signant Health to create a platform that prevented trial participants from reporting ALL unique side effects.

In order to purposefully limit a participant's input, the TrialMax "Vaccination Diary" module asked specific questions regarding ONLY the following symptoms: fever, redness at the injection site, swelling at the injection site, pain at the injection site, fatigue, headache, vomiting, diarrhea, chills, muscle pain, and joint pain. These are commonly known side effects of most vaccines.

The additional symptoms of cough, shortness of breath, loss of taste/smell, and sore throat could supplementally be recorded in the TrialMax "COVID-19 Illness Diary" module. The app, however, did not allow for any independent reporting of symptoms. Therefore, these two modules were the only places available to record any side effects. For example, if a trial participant opened the app to report experiencing possible symptoms of Guillain-Barre Syndrome; pins and needles

sensation in the toes, weakness in the legs, or difficulty with eye muscles or vision, there would be absolutely no place to record this information. And what if one experienced chest pain, facial droop, or any other unusual side effect? Pfizer did not allow the collection of ANY OTHER side effect data. They purposefully limited these participants to enter ONLY the specific side effects they asked about!

Although tracking inflammation side effects, also referred to as reactogenic side effects, is beneficial, Pfizer's primary objective here was to collect only inflammation-related side effects, and nothing else. The CDC advertises "common side effects" but limits their list to inflammation related effects only. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html In any clinical trial, however, the safety profile should refer to ALL adverse events and not just those related to inflammation. https://www.nature.com/articles/s41541-019-0132-6#Sec1 Pfizer limiting the reporting of side effects to those of inflammation appears deceptive and intentional.

In conclusion, Pfizer contracted Signant Health to intentionally collect only specific vaccine side effects through the TrialMax app. This app was the primary collection tool that allowed for quick organization of data and a significant factor in Pfizer attaining their EUA, period. They only collected the side effects that they wanted to collect, and this was willfully unethical and misleading!

Report 24: "Vaccine Trials for Infants and Children Show Little to No Benefit" by Chris Flowers, M.D. – Teams 1 and 3.

On June 15, 2022, the FDA Vaccines and Related Biological Products Advisory Committee (VRBPA) met to authorize the expansion of the EUA Pfizer BNT162b2 vaccine to children as young as 6 months. Evidence and public comments were given, but despite the FDA accepting that the evidence for this action was poor (given a grade of C), they decided to extend the EUA to this group.

Why are we concerned about young children receiving a vaccine that we have been told is 'safe and effective'?

As confirmed in a letter to the FDA committee by the Children's Health Defense (R.F. Kennedy, Jr., 2022. https://childrenshealthdefense.org/wp-content/uploads/CHD-Letter-to-FDA-VRBPAC-2022-06-10.pdf), there are virtually no deaths in children under 5 from COVID and a 99.995% recovery rate for children without an underlying condition.

The vaccine does not prevent infection or reduce transmission. Furthermore, CDC published data show a poor efficacy of 31%, reducing to 12% after seven weeks in the 5-11 year age range (Vajeera Dorabawila, PhD, Dina Hoefer, PhD, Ursula E. Bower, PhD et al., "Effectiveness of the BNT162b2 Vaccine among Children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant," medRxiv, Feb. 28, 2022. https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1). The mRNA vaccines do not stop infection, replication, or spread of the Omicron variants. They are not fulfilling their intended purpose.

How do we determine whether the benefits outweigh the risks in young children?

As infants and young children are so unlikely to be seriously ill or die from COVID, what are the potential risks? Sure, there are similar general effects following vaccination of pain and fever, but there are other rarer risks of serious adverse events, including respiratory problems and seizures. This is in addition to the effects on the Thymus (which is maturing and plays a major part in immunity in young children).

What did the Pfizer trial show?

Run at 65 trial sites, they recruited a total of 4526 children of which, 3000 children dropped out before the end of the trial.

Pfizer presented evidence that the only antibodies produced in the children were to the Wuhan (alpha strain) spike with no detectable antibodies to the Omicron variant (Craig, HART Group, 2022. https://www.hartgroup.org/fda-approve-covid-vaccine-for-0-4-years/).

However, the trial also shows other alarming results.

There were 30% more covid cases in the vaccine arm after the first dose than the placebo, so they ignored that data. The same occurred with the second and third rounds.

In total, after two months, COVID developed twice as much in the vaccinated vs placebo group, suggesting that there was a higher likelihood that the vaccine was causing severe COVID than the likelihood that it was not. In fact, 12 of the children got COVID twice, 11 of which were in the vaccination arm!

What should parents take away from the results of this trial?

There is a lack of evidence to support giving the BNT162b2 COVID vaccine to children six months to four years.

The risks vastly outweigh the benefits.

Parents should be demanding decision makers at the FDA and CDC to explain themselves as to why they ignored the data and put their child at risk from adverse events, when they are so unlikely to get severe illness or die from COVID.

Further Reading:

Dr. Craig published a video de-constructing the trial (Craig, 2022).

> https://rumble.com/v18s66i-bombshell-dr.-clare-craig-exposes-how-pfizer-twisted-their-clinical-trial
>
> https://rumble.com/v197mj7-eua-amendment-request-for-pfizer-biontech-covid-19-vaccine-for-children.html

Statement from Governor Ron DeSantis: https://youtu.be/fyad-OVxqho.

Report 25: "Did Pfizer and the FDA Conceal an Existing Remedy for COVID?" by Don – Team 4.

Did Pfizer Know Prevnar Prevented COVID?

Summary:
Research has shown that Pfizer may have known its pneumococcal drug Prevnar (PCV13) may have helped prevent COVID or SARS-COV-2 and that thus there was not a need for 'Operation Warp Speed' by the Trump Administration. Prevnar is an already-approved drug currently used to treat pneumonia. However, it has been shown to have general antiviral effects and can thus be effective in protecting against bacterial respiratory infections. Despite Prevnar being a Pfizer drug, Pfizer did not present Prevnar to the public as an option for fighting against SARS-COV-2. Additionally, the new vaccines would fall under Emergency Use Authorization, which would ensure protection from liability for Pfizer. Not only did Pfizer fail to present Prevnar to Americans as a preventative option against COVID to the public, but the FDA also failed to reveal effective uses to the public. Instead, both Pfizer and the FDA moved forward with the release of the mRNA vaccines.

Article:
Did Pfizer and the FDA know that Prevnar (PCV13) prevented SARS-COV-2? Research reveals that they did.

Pfizer's internal documents, released under court order, show that in Pfizer's phased trials for their BioNTech mRNA vaccine, the company excluded any participant from the trials who was taking *medications intended to prevent COVID-19*. The interesting thing about this exclusion is that Pfizer knew that their pneumococcal drug Prevnar may prevent COVID (SARS-COV-2) in older patients aged 65 or older. In other words, Pfizer excluded participants who were already being helped by therapeutics. Once again, in Pfizer's science, we see scientists excluding what they do not wish to find.
This screenshot from our first tranche of Pfizer documents. I have included page 29:

- Phases 1 and 2 only: Known infection with HIV, HCV, or HBV.
- History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s).
- Receipt of medications intended to prevent COVID 19.
- Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19.
- **Phase 1 only:** Individuals at high risk for severe COVID-19, including those with any of the following risk factors:

How do we know that Prevnar may prevent COVID? Prior research points to the protective effects of Prevnar (PCV13) in viral and '*bacterial respiratory diseases*.' In a retrospective study published in *The Journal of Infectious Diseases*, PCV13 also showed protective effects against SARS-COV-2 infections.
Among 531, 033 adults, there were 3677 COVID-19 diagnoses, leading to 1075 hospitalizations and 334 fatalities between March 1 and July 22, 2020.
[https://academic.oup.com/jid/advance-article/doi/10.1093/infdis/jiab128/6164926]
[https://www.infectiousdiseaseadvisor.com/home/topics/covid19/pneumococcal-conjugate-vaccine-pcv13-protective-against-sars-cov-2-infections/]

Why didn't the FDA make this revelation available to the public? Notice that this discovery was from March – July of 2020 — in other words, "*the height of the pandemic"* — and yet the public was never formally informed about this protective drug.
If the FDA had informed America about Prevnar in 2020, there would have been no need for the fast-track status that the FDA gave to drug companies to develop the mRNA vaccines for COVID. That silence could have cost lives.

[STN-125742_0_0-section-2.7.4-summary-clin-safety - https://campaigns.dailyclout.io/campaign/item/d3895929-7a27-49b8-9368-0d4bc484e646]

[https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf]

H.R. 5546 – The National Childhood Vaccine Injury Act of 1986 – established a vaccine injury schedule for pain and suffering with a maximum payment of $250,000 per incident, otherwise absolving drug companies of liability.

The Act provides that no vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death: (1) resulting from unavoidable side effects; or (2) solely due to the manufacturer's failure to provide direct warnings. It also ensures that a manufacturer may be held liable where: (1) such manufacturer engaged in the fraudulent or intentional withholding of information; or (2) such manufacturer failed to exercise due care. Lastly, it permits punitive damages under certain circumstances.

Did Pfizer engage in fraudulent or intentional withholding of information and fail to exercise "due care"? A court may well rule "yes."

We now know from Pfizer's Internal Phase 1 trials of the COVID vaccine, the company identified "receipt of medications intended to prevent COVID-19."

The above evidence may well prove that Pfizer knew that medications such as Prevnar could indeed prevent COVID-19 and this knowledge should have been revealed to the world before thousands died. What did Pfizer and the FDA know and when did they know it?

Report 26: "Inconsistencies in Pfizer Clinical Trials Are Surfacing" by Sean Ludford.

Summary:
This report is based on the currently released Pfizer documents. There is evidence to support that, at the start of the clinical trials, there were two groups. One group was given the vaccine, the other was given a placebo. However, contrary to the usual practice of spacing out the timing to account for side effects, only four months after the second group was given a placebo, the vaccine was administered to them. Because of this, there would have been no way to tell if the vaccinated group was experiencing side effects if the placebo group was given the vaccine as well, thus eliminating the control group. Analysis on this will continue as new documents are released.

I would like to share my findings based on three FDA-released Pfizer documents: 125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf (Demographic File), 125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf (Two Shots File), and 125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf (Four Shots File). Please refer to the end of this document for a full description of these three files.

I have also discovered numerous files (greater than a dozen) that have repetitive information to the three files that I have converted to a database. It's unclear if these files were documents used internally or simply documents exported from their database and presented in a slightly different form.

The *Demographic File* [125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf] was the first discovery. Presented from Pfizer as a nearly 3,000-page document, it seemed far too daunting a task to make any discoveries in that document form. The flat file was converted to a fully searchable database. I created the database using the Filemaker Pro application. This is a well-known and respected database application with a 37-year history.

I initially believed that there was a unique identifier (an ID number) to be found within each record presented in the Demographic File. This proved to be true. I further believed that there would be additional documents revealed in the future that would be related to the Demographic File allowing us to track the subjects introduced in the Demographic File. This also proved to be true.

Next, I found a similar file called, *Two Shots File* for short.[125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf] This PDF followed a similar format to the Demographic File [125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf] and, most importantly, it included the unique ID number. After converting the Two Shots File to database form, I was able to create a relationship between the Demographic File[125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf] and the Two Shots File [125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf] based on the ID number. This provided a subject's demographic

information, as well as information regarding their first two test shots. Subjects were placed in "Randomization Vaccine Groups" that included a "Placebo" group. The dose of each shot given to the test subjects was also recorded.

Next, I discovered a similar file called, *Four Shots File* for short.[125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf] This PDF followed a similar format to the Demographic File [125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf] and Two Shots File [125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf] and again it importantly included the unique ID number. After converting the Four Shots File [125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf] to database form I was able to create a relationship between the three files based on the ID number. Further, the second two files also include a "Randomization Number" that is also unique to each subject. This provided a subject's demographic information, as well as information regarding their first four test shots.

However, not all subjects were given a third and fourth shot. Shockingly, *only* the Placebo group were given third and fourth shots — with actual vaccine, not a placebo. These third and fourth shots were identified with a vaccine group value (consistent with the previously vaccinated subjects) and a designated dose. In this case, all the doses were 30 micrograms.

Just four months after entering the trial and being given a placebo, the Placebo Group was given the vaccine, thus eliminating a control group. I am not a doctor, but this seems to make the entire trial null and void.

I consider this an ongoing investigation, and I will be examining current and future document releases to find more related data.

Other Related Findings

I found 625 subjects included in the Four Shots File [125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf] that were not in the Two Shots File [125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf]. 428 (77%) of these 625 subjects are under the age of 18. I'm not sure if this is significant or if it has any significance that these subjects were not included in the Two Shots File.[125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf] Based on the data, they should have been included as they received either a vaccine or a placebo.

The Two Shots File [125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf] reveals that 2,449 subjects were given the first shot but not a second shot. No explanation is given.

Among the 19,645 subjects in the Placebo Group who received a third shot of 30 micrograms of vaccine, 3,626 did not receive a fourth. No explanation is given.

In all three files the "Subject" field offers one of 154 unique values for a respective test subject. The second of three numbers expressed here appears to be a physical/geographic test location. I have a breakdown of the number of subjects that hail from each site.

About the three Pfizer files I have used:

125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf (Demographic File)
[125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf]
Downloaded from the DailyClout site on April 11, 2022

This file is 2,951 pages in length and contains 44,257 unique records. Within the document the data is described in the header as: "16.2.4 Listing of Demographic Characteristics – All Subjects ≥16 Years of Age."

The information provided is organized in 11 fields as follows:

1. "Age Group (Years)" — This field is blank with the exception of:

Page 1 – record 1 of 15, value = "16-55"
Page 1745 – record 12 of 15, value = "18-55"
Page 1752 – record 12 of 15, value = "65-85"
Page 1758 – record 12 of 15, value = ">55"

2. "Subject" — This field contains three sets of values. The first is an eight-character, alphanumeric value = "C4591001" that is constant in all records. Next is a four-digit number that is not unique to each record. There are 154 unique four-digit numbers in this second value. It is now understood that this number represents a test location. Third is an eight-digit number that is unique to each record. Among the 44,257 records this number does not repeat. Once this was discovered, I considered this number to be the subject's unique ID number hoping that it would appear in future files giving a basis to track individual subjects.
3. "Age (Years)" — the subject's age expressed in two digits ranging from 15 to 91.
4. "Sex" — expressed as Male or Female
5. "Height (cm)" — height expressed in centimeters
6. "Weight (kg)" — weight expressed in kilograms
7. "Body Mass Index (BMI)" — expressed numerically rounded to one decimal
8. "Race"
9. "Racial Designation" — most often left blank
10. "Ethnicity"
11. "Informed Consent Date (Screening)" — date expressed, example, 26AUG2020

125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf (Two Shots File)
[125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf**]**
Downloaded from the DailyClout site on April 18, 2022
This file is 4,412 pages in length and contains 43,746 unique records. This document is two documents in one file. The first 37 pages are described in the header as: "16.1.7.2 Listing of Randomization Scheme and Actual Vaccine Received – Phase 2."
Pages 38 through 4,412 are described in the header as: "16.1.7.4 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects."
It's unclear why this document is in two parts especially when considering that the first 37 pages contain data that is exactly duplicated in the following pages.

The information provided is organized in 10 fields as follows:

1. "Subject Study Identifier" — This field is the third eight-digit number that I had previously identified as a unique ID number.
2. "Subject" — same as "Subject" in the previous file.
3. "Age Group (Years)" — expressed as an age range, for example, 18-55.
4. "Randomization Date" — date expressed, example, 26AUG2020.
5. "Randomization Number" — a second unique ID number expressed as a four-to-six-digit number.
6. "Randomization Vaccine Group" — expressed as eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = "Placebo."
7. "Date" — date of first dose expressed as previous dates.
8. "Dose 1" — expressed as eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = "Placebo."
9. "Date" — date of second dose expressed as previous dates.
10. "Dose 2" — expressed as eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = "Placebo."

125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf (Four Shots File)
[125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf**]**
Downloaded from the DailyClout site on May 4, 2022
This file is 4,376 pages in length and contains 44,360 unique records. Within the document the data is described in the header as: "16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age."

The information provided is organized in 10 fields as follows:

1. "Subject Study Identifier" — This field is the third eight-digit number that I had previously identified as a unique ID number.
2. "Subject" — same as "Subject" in previous files.
3. "Age Group (Years)" — expressed as an age range, example, 18-5.

4. “Randomization Date” — date expressed, example, 26AUG2020.
5. “Randomization Number” — a second unique ID number expressed as a four-to-six-digit number.
6. “Randomization Vaccine Group” — expressed as eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = “Placebo.”
7. “Date/Dose 1” — date of first dose expressed as previous dates with an eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = “Placebo.”
8. “Date/Dose 2” — date of second dose expressed as previous dates with an eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = “Placebo.”
9. “Date/Dose 3” — date of third dose expressed as previous dates with an eight-character, alphanumeric value, as well as a dose expressed in micrograms.
10. “Date/Dose 4” — date of fourth dose expressed as previous dates with an eight-character, alphanumeric value, as well as a dose expressed in micrograms.

All data presented to the best of my understanding.

Report 27: "Pfizer-BioNTech 'Equivalent' Half Truths or a 'Lot' of Lies?" by Kathleen Willis, MD.

Summary

1. The public was not told only four percent of Pfizer lots were "equivalent/interchangeable."
2. Pfizer published a letter (still online) to healthcare professionals stating only certain lots met the "equivalent/interchangeable" criteria.
3. Due to the lack of disclosure, the public falsely believed that the Pfizer-BioNTech vaccine available in the United States was all equal to the approved Comirnaty. Due to this belief, and their assumption that mandates were legal if not under an EUA, they complied and took the genetic therapy to keep their jobs. Legal precedent was set based on information provided by Pfizer and the FDA in regard to the "equivalent/interchangeable" narrative. As far as I know, the courts were not aware that only four percent of the lots met the criteria. If they had, it would've been impossible to rule in favor of a vaccine mandate as there wouldn't have been enough of the "FDA approved equivalent/interchangeable" genetic therapy to distribute to all parties who were being required to take it. Our military has been decimated with ADE's as well as disciplinary actions and dismissals due to refusal to take the genetic therapy. The actions taken by military leadership was based on the "equivalent/interchangeable" narrative as evidenced by their order requiring all military to comply with the genetic therapy on Aug 24, 2021, the day after the FDA approval of Comirnaty. This is a serious national security threat.
4. Pfizer, FDA and CDC need to answer why this information was not released to the public instead of implying that all vaccines in the US were the same as Comirnaty.
5. This is fraud of the highest order. The scale of this deception is massive, and the collateral damage is far and wide. Improperly imposed mandates based on deception, court cases decided with incomplete information, decimation of our military due to ADEs.

In the Fall of 2021, the Food and Drug Administration (FDA) approved Pfizer's COVID-19 vaccine which led to extensive policy changes, imposed mandates, societal conflict, job loss, discrimination and much more. The country was turned upside down. Government health agencies whom we have depended on for medical expertise and truth failed us. This failure resulted in unnecessary policy changes and mandates that caused job losses and worse. Whether intentional or otherwise, our trusted agencies left out a small but significant detail that would have stopped the mandates.

On August 23, 2021, the FDA announced the approval of Pfizer-BioNTech's Biologics License Application (BLA) for Comirnaty, a branded mRNA COVID-19 vaccine. The FDA reported that the Pfizer-BioNTech FDA-approved product, Comirnaty, and the Pfizer-BioNTech Emergency Use Authorization (EUA) product were equivalent and could be used interchangeably. The public heard this ad nauseam from health officials in public briefings, news articles and even government committee hearings.

FDA grants full approval to Pfizer/BioNTech Covid-19 vaccine, opening door to more vaccine mandates

By Jacqueline Howard, CNN
Updated 12:25 PM EDT, Mon August 23, 2021

"Health care providers can continue to use the vaccine on their shelves," Woodcock added. "The FDA-approved vaccine and the EUA-authorized vaccine have the same formulation and can be used interchangeably to provide the Covid-19 vaccine series."

However, that was not the whole story. A pertinent disclaimer was left out of the announcement as evidenced by a document Pfizer quietly posted on their website dated Aug 23, 2021, the same day as of the FDA approval announcement. The subject line says it all. *"Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA)."* Screenshot below.

August 23, 2021
RE: Pfizer-BioNTech COVID-19 Vaccine IMPORTANT PRODUCT INFORMATION
Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA)

COMIRNATY
(COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229

Dear Healthcare Professional,
Pfizer, Inc. would like to provide you with updated and very important information related to the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use by FDA under an Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech's Biologics License Application (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 2229. Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered "BLA-approved" lots for administration to individuals 16 years of age and older.** The lots that are BLA-approved for administration may be found at cvdvaccine-us.com/resources. For these lots, please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information. This information can be found by scanning the QR code. **Please note, it is imperative that you not discard any available EUA lots. These lots continue to be authorized for use under EUA in individuals 12 years of age and older, and for use as a third dose in certain immunocompromised individuals. You can continue to use them up to the date of expiry.**

Sincerely,

Donna Boyce
Senior Vice President, Global Regulatory Affairs

BIONTECH

Pfizer

2021TA035 v1.0

If you plan to redistribute the Pfizer-BioNTech COVID-19 Vaccine, please read on...

COMIRNATY
(COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229

WHAT?	If you plan on redistributing the Pfizer-BioNTech COVID-19 Vaccine, you must include at least one copy of the letter with QR code in each of the smaller, portable packaging containers being used for transport.
WHY?	Once the Pfizer-BioNTech COVID-19 Vaccine arrives at its final destination, the QR code may be used to look up the lot number on the carton to determine if the product is BLA-approved.
HOW?	To create additional copies of the letter to include in smaller transport containers, you may: • Make copies of this letter using a copy machine • Make printouts by visiting cvdvaccine-us.com/resources

For questions related to this notification please contact
Pfizer Customer Service at 1-800-666-7248.

BIONTECH

Pfizer

2021TA035 v1.0

The letter states, *"Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use and are labeled in accordance with the EUA.* ***Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered "BLA-approved" lots for administration to individuals 16 years of age and older."*** The corresponding lot numbers were not included in the letter. Rather, a website was provided to access the information, which was not easy to find. The letter also stated that the QR code was intended to provide direct access to prescribing information, indication and usage, dosing and administration and other important safety information. However, accessing the QR code produced the lot numbers instead. It seems Pfizer may have made an error and reversed the link and QR code in their instructions. Here are the lot numbers posted on Pfizer's webpage:

Additional Lot Details – Lot Numbers

FD7220
FE3592
FF2587
FF2588
FF2590
FF2593
FF8841
FH8027
FH8028

***This author was told by the Pfizer representative on the phone that all of these lots were purple cap vials.**

Only nine lot numbers are "equivalent" to the FDA approved COMIRNATY.

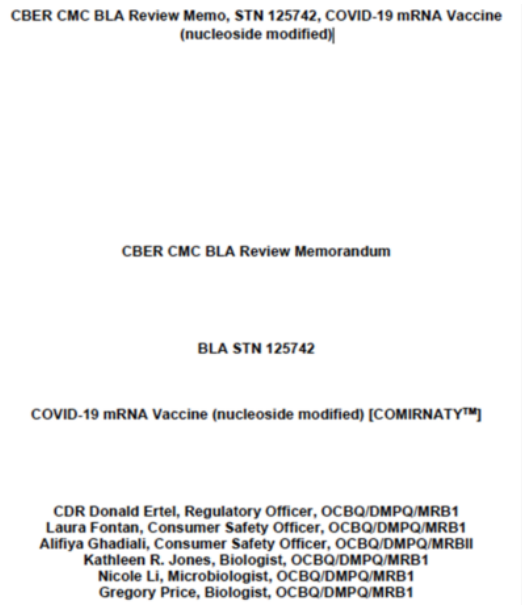
There are only nine. These are the lot numbers that are "equivalent" and "interchangeable," per the letter, but what makes them different from the other Pfizer-BioNTech EUA lots? This author had multiple communications with Pfizer via email and/or phone on the following dates: October 11, 2021; February 7, 2022; February 8, 2022; Apr 14, 2022; and May 13, 2022. In a follow-up email after one of the calls, Pfizer sent an explanation of the difference. See screenshot below of paragraph from their email.

- While the products are manufactured using the same processes, they may have been manufactured at different sites or using raw materials from different approved suppliers. FDA closely reviews all manufacturing steps and has found explicitly that the EUA and BLA products are equivalent.[7]

Pay close attention to the verbiage here. It states that the processes are the same. *"While the products are manufactured using the same process, they may have been manufactured at different sites or using raw materials from different approved suppliers."* Therefore, according to Pfizer's explanation, the variables that differentiate the "equivalent" version from others is where they are manufactured, and the raw materials used. In another email, they sent information seen in the screenshot below. This time it states the ingredients and process are the same; therefore, the facility would be the only variable that is different.

- In terms of its ingredients and how it is made, the vaccine FDA-approved for those 16 years and older is no different from the vaccine that has been administered under the Emergency Use Authorization (EUA). [1]

On page nine of the Pfizer document titled *CBER CMC BLA Review Memo, STN 125742, COVID-19 mRNA Vaccine (nucleoside modified)* that was submitted with their COMIRNATY approval application, it states, *"Note, the facilities proposed for use to manufacture COMIRNATY™ under the BLA are facilities that are used to manufacture the Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA), which was originally issued on December 11, 2020. However, not all facilities used to manufacture the Pfizer-BioNTech COVID-19 Vaccine under EUA are proposed for use under the BLA."* Screen shot of cover page below. This supports what Pfizer said over the phone and in follow-up emails as stated above.



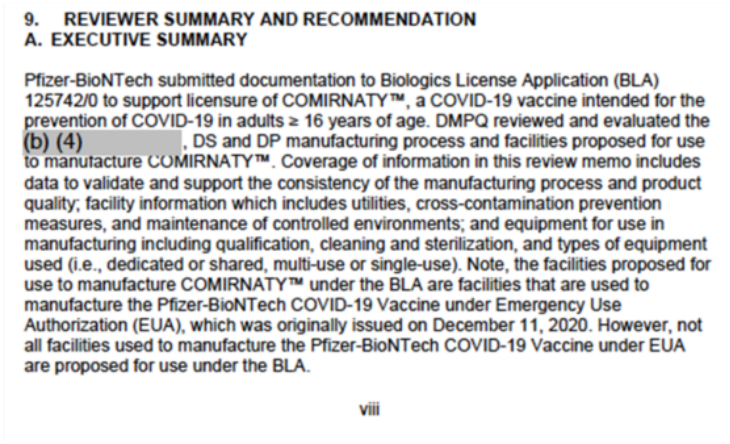
CBER CMC BLA Review Memo, STN 125742, COVID-19 mRNA Vaccine (nucleoside modified)

CBER CMC BLA Review Memorandum

BLA STN 125742

COVID-19 mRNA Vaccine (nucleoside modified) [COMIRNATY™]

CDR Donald Ertel, Regulatory Officer, OCBQ/DMPQ/MRB1
Laura Fontan, Consumer Safety Officer, OCBQ/DMPQ/MRB1
Alifiya Ghadiali, Consumer Safety Officer, OCBQ/DMPQ/MRBII
Kathleen R. Jones, Biologist, OCBQ/DMPQ/MRB1
Nicole Li, Microbiologist, OCBQ/DMPQ/MRB1
Gregory Price, Biologist, OCBQ/DMPQ/MRB1



9. REVIEWER SUMMARY AND RECOMMENDATION
A. EXECUTIVE SUMMARY

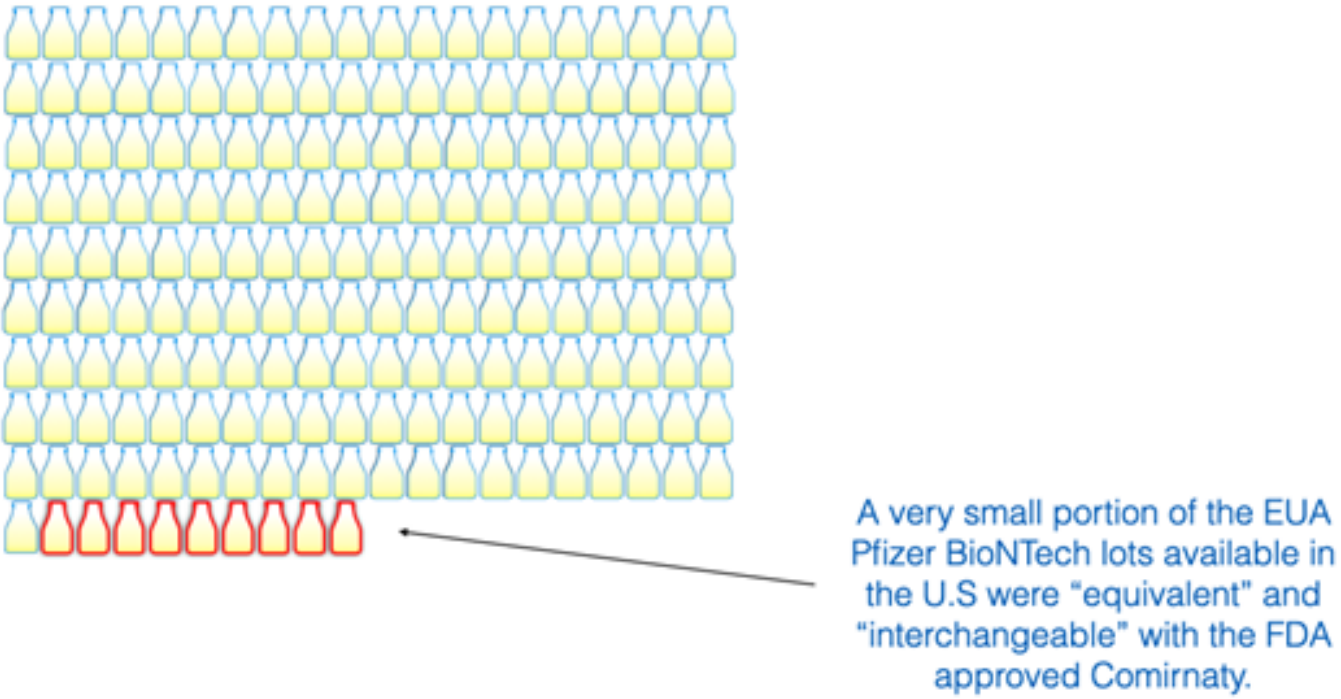
Pfizer-BioNTech submitted documentation to Biologics License Application (BLA) 125742/0 to support licensure of COMIRNATY™, a COVID-19 vaccine intended for the prevention of COVID-19 in adults ≥ 16 years of age. DMPQ reviewed and evaluated the (b) (4), DS and DP manufacturing process and facilities proposed for use to manufacture COMIRNATY™. Coverage of information in this review memo includes data to validate and support the consistency of the manufacturing process and product quality; facility information which includes utilities, cross-contamination prevention measures, and maintenance of controlled environments; and equipment for use in manufacturing including qualification, cleaning and sterilization, and types of equipment used (i.e., dedicated or shared, multi-use or single-use). Note, the facilities proposed for use to manufacture COMIRNATY™ under the BLA are facilities that are used to manufacture the Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA), which was originally issued on December 11, 2020. However, not all facilities used to manufacture the Pfizer-BioNTech COVID-19 Vaccine under EUA are proposed for use under the BLA.

viii

Also, of note in the same document, is the description of evaluating quality control measures at the manufacturing facilities, such as cross contamination prevention measures, maintenance of controlled environments, cleaning and sterilization, etc. Based on this information, it seems logical that Pfizer would only submit for FDA approval with facilities that met the quality standards described in the Biologics License Application. This begs the question, were there quality issues with other facilities that were making the majority of the product circulating in the United States?

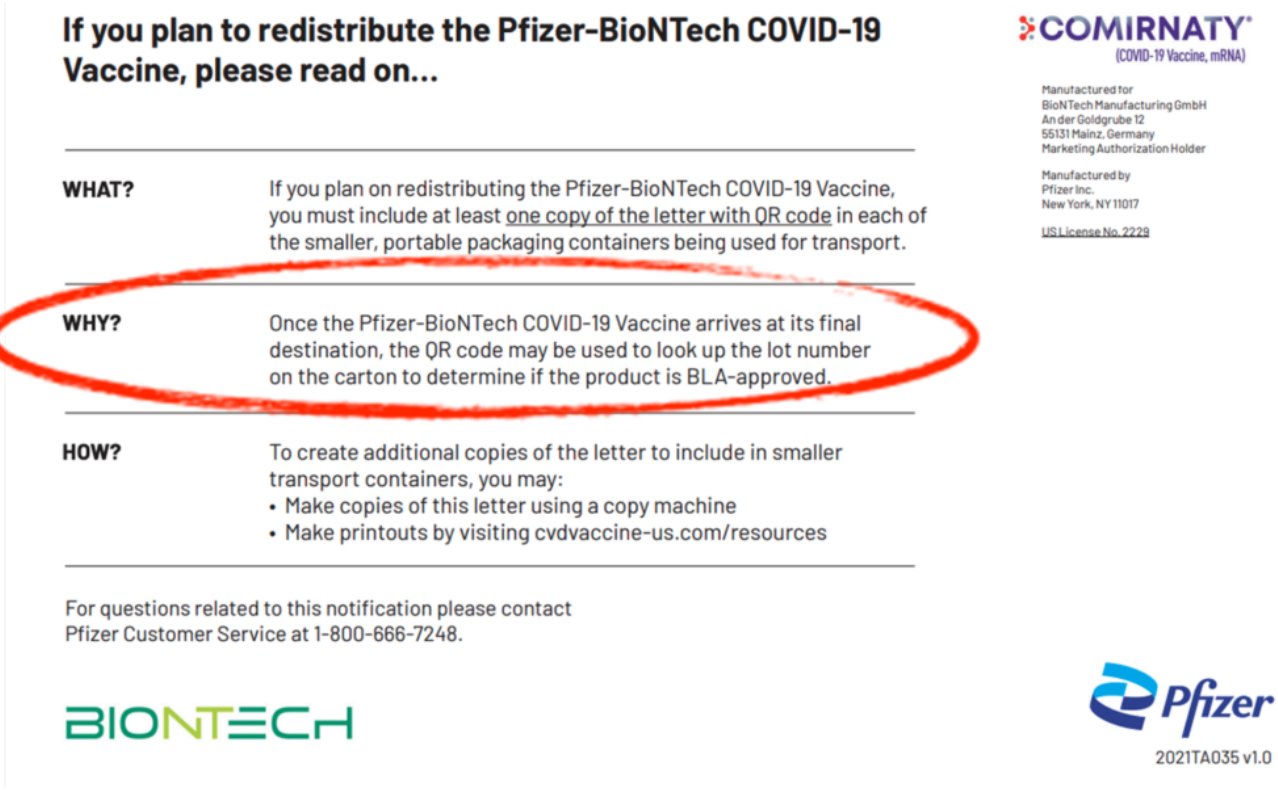
If there are quality differences, and only the "equivalent" lots were produced in facilities that met quality standards, what was the chance of getting the FDA-approved "equivalent" product?

We can calculate that chance using a June 14, 2022, document leaked by a Centers for Disease Control and Prevention (CDC) staff member to the *How Bad Is My Batch?* website [https://howbadismybatch.com/]. The document showed a total of 190 Pfizer lots. Although it would be more accurate to use the number of doses for the calculation, that information is not publicly available. The graphic below helps to put this in perspective visually.



This indicates that potentially very few people got the "interchangeable" formula that is supposed to be "equivalent" to the FDA-approved version of the Pfizer vaccine. If there were 190 lots available in the United States and only nine met the "equivalent" criteria, that would be a 4.7% chance of receiving the equivalent formulation.

There is another important thing to note on the second page of the letter where distribution is addressed. Here is the screenshot again:



If you plan to redistribute the Pfizer-BioNTech COVID-19 Vaccine, please read on...

COMIRNATY (COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229

WHAT?	If you plan on redistributing the Pfizer-BioNTech COVID-19 Vaccine, you must include at least one copy of the letter with QR code in each of the smaller, portable packaging containers being used for transport.
WHY?	Once the Pfizer-BioNTech COVID-19 Vaccine arrives at its final destination, the QR code may be used to look up the lot number on the carton to determine if the product is BLA-approved.
HOW?	To create additional copies of the letter to include in smaller transport containers, you may: • Make copies of this letter using a copy machine • Make printouts by visiting cvdvaccine-us.com/resources

For questions related to this notification please contact
Pfizer Customer Service at 1-800-666-7248.

BIONTECH

Pfizer

2021TA035 v1.0

It states that if unused product is going to be shipped to another location, the shipment must include a copy of the letter with the QR code, referenced on the second page of this report, so that it can be *used to determine if the lot number on the carton is the BLA-approved product*. To know and follow this requirement, one must know the letter exists. This author has spoken to several physicians and pharmacists, and none have been aware of the letter.

SPECIAL INFORMATION FOR CHILDREN: **Please note, according to the Pfizer representative via phone, the nine lots equivalent to the FDA-approved Comirnaty are all purple cap vials for ages 16 years and older. Therefore, these nine lots would not be suitable for the newly authorized age range of 6 months to 5 years old. There is no formula that is "equivalent" to FDA-approved version for children under the age of 16.**

The bottom line?

Americans are being deceived. Public disclosure has not been given. Only some of the available lots are "equivalent." The chances of getting the "equivalent" formulation are very slim. Americans were led to believe that *all* the Pfizer-BioNTech vaccines were "equivalent" and "interchangeable" with the FDA-approved product, which is not at all the case.

This lack of transparency led to a tidal wave of policy changes, including vaccine mandates, thus destroying many Americans' lives. People lost their jobs. Students were not allowed to attend colleges. Soldiers were kicked out of the military. Americans were prevented from entering businesses, sporting events, and much more. If this information had been publicly available and widely disseminated, COVID-19 vaccine-related court cases may have played out much differently. Additionally, military leaders may have made much different choices. Unfortunately, we do not get a do-over.

The most important takeaway is that the American public was lied to. That is truly all we need to know. In 23 years of medicine, this may be the most unethical thing this author has seen. It will take decades for healthcare to recover from the damage that has been done.

Report 28: "If Pfizer Controlled the 'Data,' They Controlled the Outcome" by Ed Clark – Team 3.

Those in Control of the 'Data' Control the Outcome

I am a participant in the independent study to review the Pfizer vaccine documents currently being released under FOIA request by the Public Health and Medical Professionals for Transparency (PHMPT) and now enforced by a Federal Judge Mark Pittman (Greene, 2022). One of the released documents sheds some light on events previously hidden from the public and demonstrates Pfizer BioNTech's effort to achieve the level of efficacy needed for a vaccine preventing SARS-CoV-2 unleashed unfavorable side effects that make the experimental gene therapy shots not safe for humans. [reissue_5.3.6 post marketing experience.pdf - https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-

The post-marketing experience document marked as 'Confidential' offers insight into the biological associated risk or adverse reaction(s) [ADRs] with the Pfizer BioNTech vaccine. These are also categorized as adverse events [AEs], serious adverse events [SAEs] , adverse events of special interest [AESIs] or just events. The telling information is presented in Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval [thru 28 February 2021].[https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf] This table shows there were 42,086 relevant [patient] cases containing a whopping 158,893 adverse events. The cases shown are broken down into three categories: Gender, Age range and Case outcome. 7.1% or 2,290 cases have No Data for Gender; 16% or 6,876 cases list Age unknown; and 23% or 9,400 cases list an Unknown outcome. It gets worse: 46.5% or 19,582 cases Recovered/Recovering were mixed together. The most revealing number of cases was 1,223 [2.91%], patients with 'Fatal' outcomes.

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

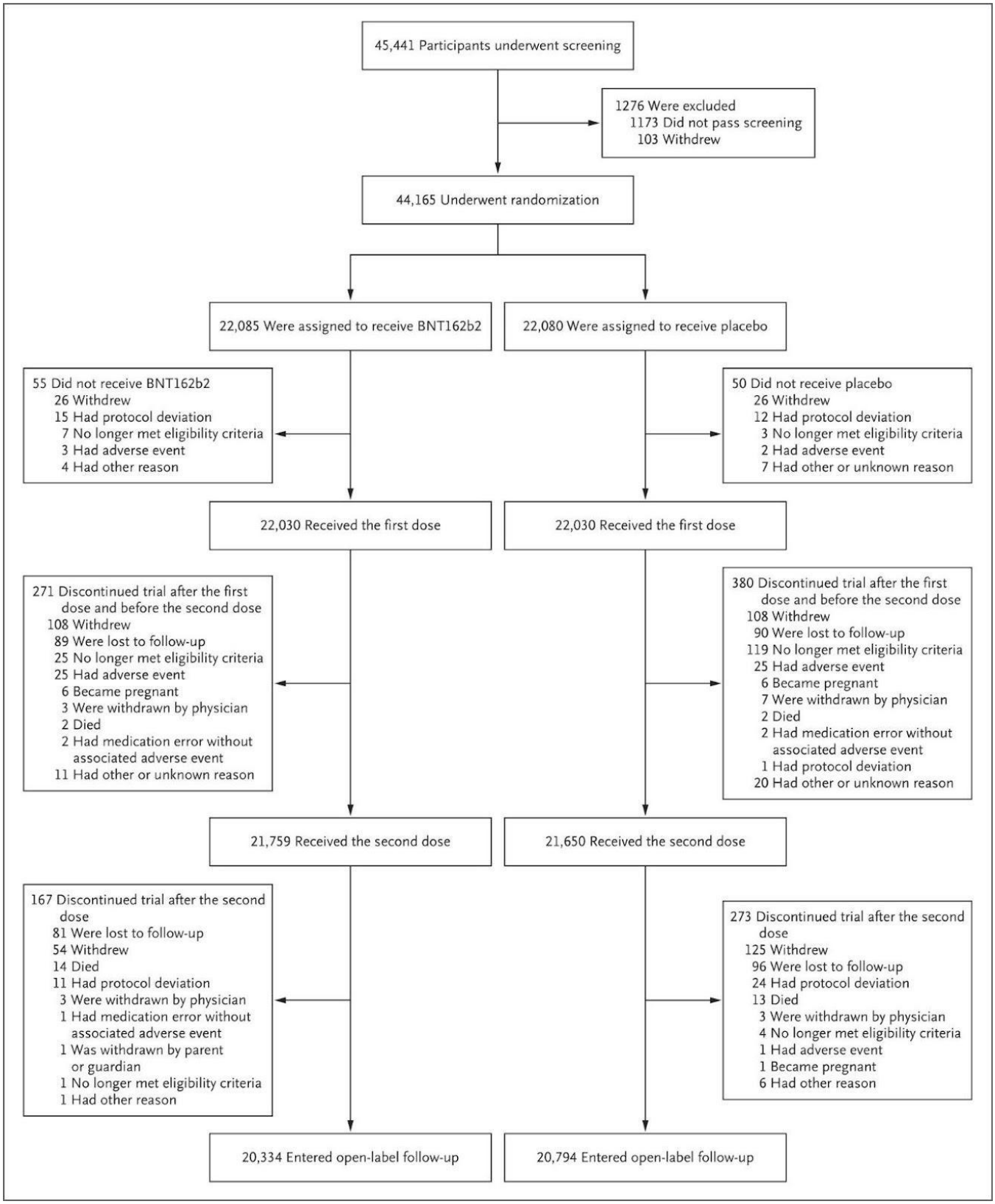
Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

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 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
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).

In comparison, a public report in the *New England Journal of Medicine* (NEJM) covering the same pivotal Phase 3 clinical trial shows that after 22,030 patients received Dose 1 [BNT162b2 vaccine], 25 had AE, 2 died, 6 became pregnant and, coincidently, for the 21,650 Placebo patients, 25 had AE, 2 died and 6 became pregnant. Following Dose 2, including 21,759 BNT162b2 recipients, no AEs, 14 died, no pregnancies; and for Placebo, 1 AE, 13 died, 1 became pregnant. The end result for BNT162b2 arm was 25 AEs, 16 deaths, 6 pregnancies; and, for Placebo arm, 26 AEs, 15 deaths, 7 pregnancies. Even the public document could not explain what happened to 1,841 missing patients I calculated from the given data after the remaining 41,128 patients entered the open-label follow-up phase (Thomas, 2021).


45,441 Participants underwent screening
1276 Were excluded
1173 Did not pass screening
103 Withdrew
44,165 Underwent randomization
22,085 Were assigned to receive BNT162b2
22,080 Were assigned to receive placebo
55 Did not receive BNT162b2
26 Withdrew
15 Had protocol deviation
7 No longer met eligibility criteria
3 Had adverse event
4 Had other reason
50 Did not receive placebo
26 Withdrew
12 Had protocol deviation
3 No longer met eligibility criteria
2 Had adverse event
7 Had other or unknown reason
22,030 Received the first dose
22,030 Received the first dose
271 Discontinued trial after the first dose and before the second dose
108 Withdrew
89 Were lost to follow-up
25 No longer met eligibility criteria
25 Had adverse event
6 Became pregnant
3 Were withdrawn by physician
2 Died
2 Had medication error without associated adverse event
11 Had other or unknown reason
380 Discontinued trial after the first dose and before the second dose
108 Withdrew
90 Were lost to follow-up
119 No longer met eligibility criteria
25 Had adverse event
6 Became pregnant
7 Were withdrawn by physician
2 Died
2 Had medication error without associated adverse event
1 Had protocol deviation
20 Had other or unknown reason
21,759 Received the second dose
21,650 Received the second dose
167 Discontinued trial after the second dose
81 Were lost to follow-up
54 Withdrew
14 Died
11 Had protocol deviation
3 Were withdrawn by physician
1 Had medication error without associated adverse event
1 Was withdrawn by parent or guardian
1 No longer met eligibility criteria
1 Had other reason
273 Discontinued trial after the second dose
125 Withdrew
96 Were lost to follow-up
24 Had protocol deviation
13 Died
3 Were withdrawn by physician
4 No longer met eligibility criteria
1 Had adverse event
1 Became pregnant
6 Had other reason
20,334 Entered open-label follow-up
20,794 Entered open-label follow-up

Prior to 07 March 2022, a recurring theme now losing its grip is 'those in control of the data control the outcome.' Pfizer/BioNTech, ICON, Penn [patent] FDA, CDC, foreign enterprise (Fosun), media [NEJM] et al, were in total control of the data, including the original research, raw data captured from human clinical trials, and supportive reports authored primarily by Pfizer employees vested in stock/stock options. More importantly, the founders of BioNTech, all with significant conflicts of interest, played an important role in ensuring a BNT162b2 vaccine approved solution. Now, with the rollout of the real data, panic is setting in. The people involved are losing control fast. After seeing the first trove of documents like the post-marketing document[https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf], it appears a CYA "clean-up" operation is taking place, a term gleaned from Brook Jackson, a whistleblower suing Pfizer and FDA (New School News, 2022). The data is not backed by science, but by the appearance of science.

While sifting through the miasma of puzzling data, I zeroed in on the number of female cases, 29,914 that stood out among the others; 3 times greater than the 9,182 male cases. This is significant as global gender rates are slightly male-biased, (Sex ratio at birth, 1950 to 2017, 2022). If the numbers hold true, one should find a similar female bias for AEs on the VAERS website. The query parameters included: Pfizer/BioNTech Vaccine US and Territories, Male and Female, all cases for the periods given in below Table.

Period	**Male AE BNT162b2**	**Female AE BNT162b2**	**Ratio**
11-31 Dec 2020	10,586	40,774	3.85:1 Female bias
01 Jan – 31 Dec 2021	318,169	665,695	2.09:1 Female bias
Combined 13-month period	328,755	706,469	2.15: 1 Female bias

The VAERS response offered a close match with Pfizer's numbers compiled for Dec 2020, trending down a data point through the next 12 months. Accumulative ratio > 2:1 Female bias.[CDC WONDER. 2022. Male / Female Adverse Events Dec 2020 - Dec 2021 COVID19 Pfizer BioNTech. [online] Available at: https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=BF991AE0B02C34DC001DEED02ADB [Accessed 19 May 2022].

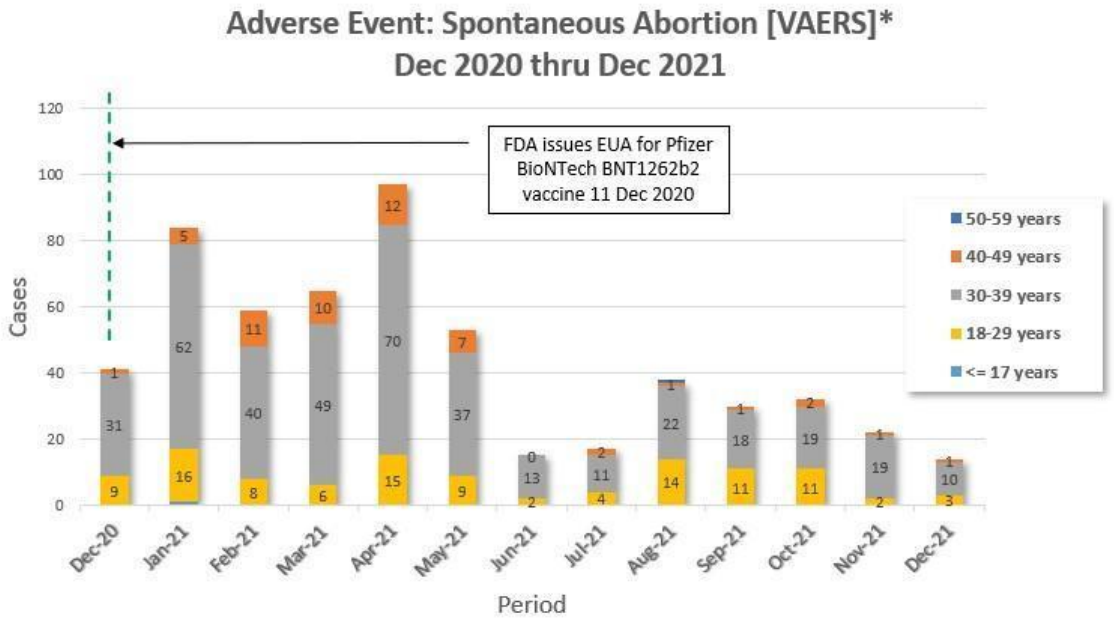
Given the higher number of biological risks associated with the Pfizer BioNTech vaccine for females, I looked at reproduction and its related AEs and targeted the less-observed event, 'Spontaneous Abortion' [Miscarriage]. Miscarriage will always be one of the more difficult injuries to establish a causal relationship with the Pfizer BioNTech vaccine since it has a rate of approximately 12% for the general population according to Mayo Clinic (Funke, 2021). Moreover, Pfizer will fall on their sword arguing research shows vaccines are not linked to miscarriages (Funke, 2021). Looking at the other side of the story, the heavily censored Dr. Joseph Mercola dismissed the Centers for Disease Control (CDC) researchers behind the study cited by Mayo Clinic, claiming "the data actually indicated miscarriage occurred in at least 82% of people vaccinated

within the first 20 weeks of pregnancy" (Funke,2021). To explore Dr. Mercola's argument, a query for AE data [Spontaneous Abortion, COVID-19, Pfizer/BioNTech, Female, US / Territories, 11Dec2020-31Dec2021] was pulled from the Wonder VAERS site. [https://wonder.cdc.gov/controller/datarequest/D8]

In the first table you will see 567 cases, each representing a patient that had a 'Spontaneous Abortion' [Miscarriage] after receiving the BNT162b2 vaccine. The period covered was 11 December 2020 (EUA start date] thru 31 December 2021.

Spontaneous Abortion – BNT162b2 (Dec 2020- Dec 2021) USA

- Search in VAERS for Adverse Events and Pfizer BioNTech [BNT162b2] vaccine discovered 567 cases where patients had a 'Spontaneous Abortion' [Miscarriage] after receiving the BNT162b2 vaccine. Period: 11 December 2020 thru 31 December 2021. [VARES].*



* VARES; accessed at http://wonder.cdc.gov/vaers.html on May 2, 2022 10:51:52 PM

1

The focus of the second chart shows the number of days to onset of miscarriage. This query was for Spontaneous Abortion [0-121+ days]. The chart shows the onset of 96 spontaneous abortions happened within 24 hours of the Pfizer BioNTech BNT162b2 vaccine, a red flag finding that should not go unnoticed. When you look deeper, the next chart starts to reveal the why behind the cause and deadly effect. CDC WONDER. 2022. Spontaneous Abortion - 567 Cases - 101 Serious - US / Territories 2021. [online] Available at: https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=BF991AE0B02C34DC001DEED02ADB [Accessed 19 May 2022].

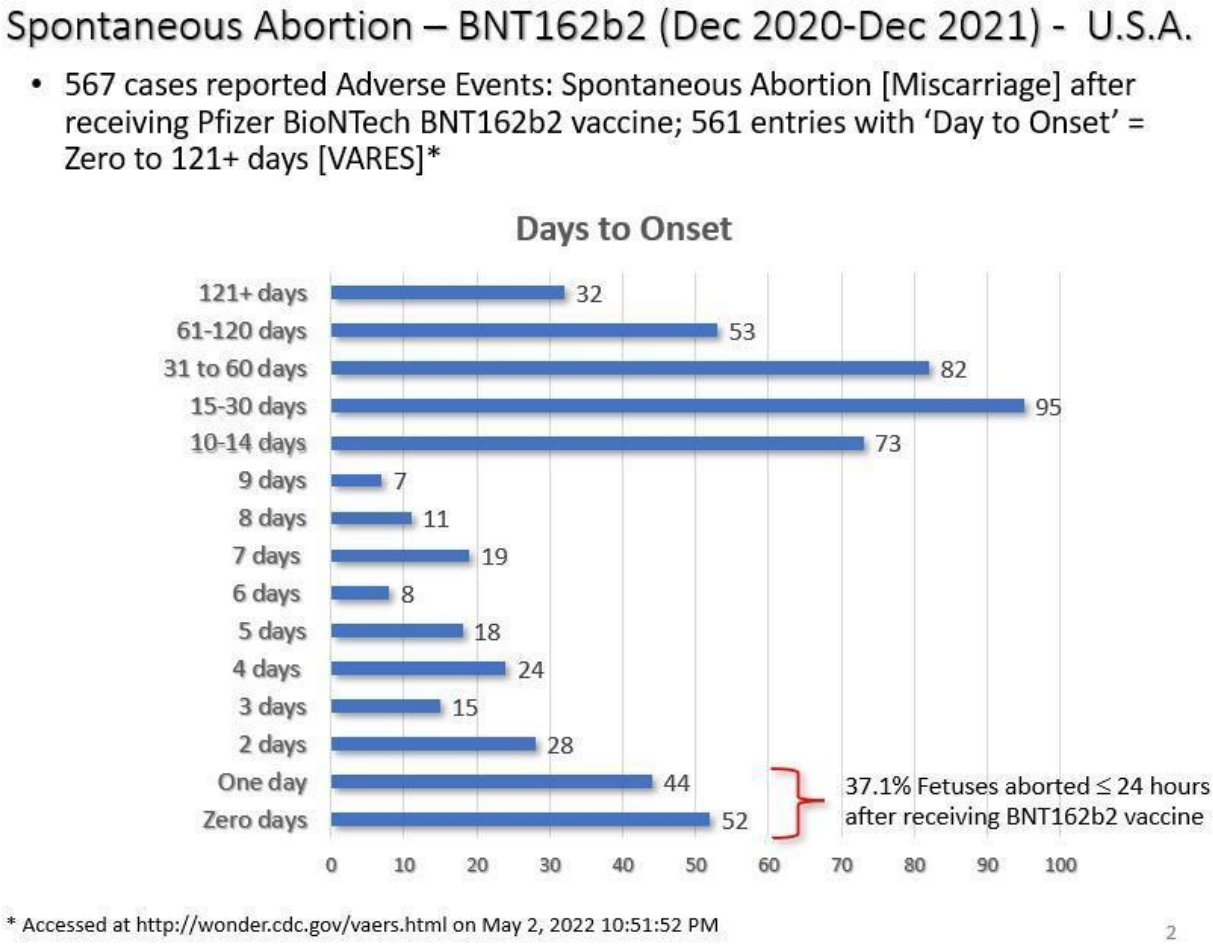
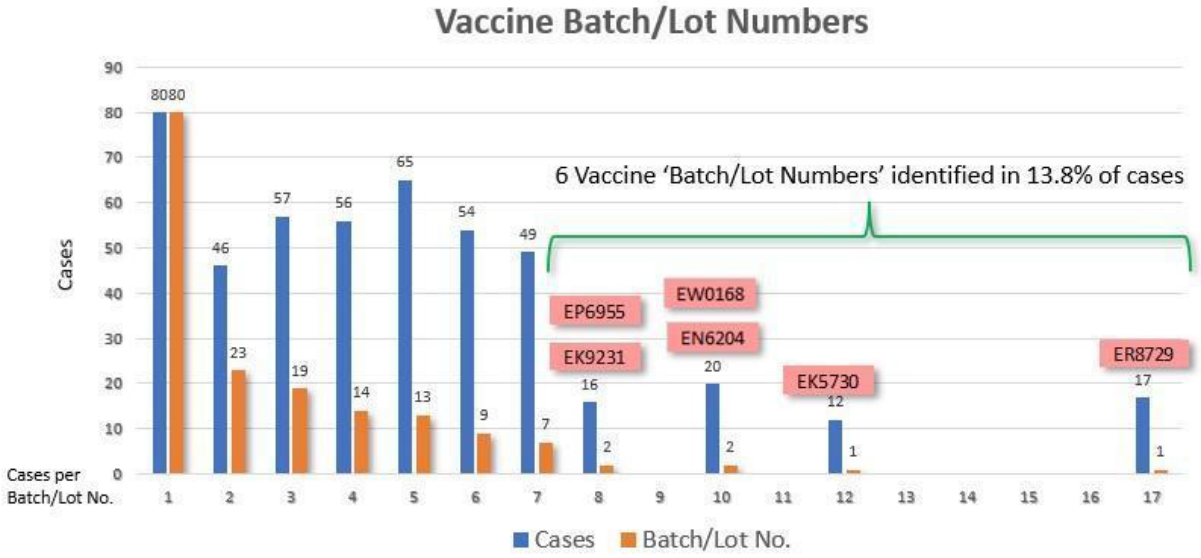


Chart 3 represents the BNT162b2 vaccine Batch/Lot numbers linked to the Spontaneous Abortion [Miscarriage]. The Batch/Lot alphanumeric code is printed on each vial that leaves the factory. It provides a receipt or chain-of-custody that follows from the plant where it was produced to the site where it was processed (thawed, diluted) and immediately injected into the patient. (Lot Release, 2022). I queried four items: Adverse Reactions (ADRs), Death, Disabilities, and Life-threatening illness (see chart CDC WONDER. 2022. Spontaneous Abortion - 567 Cases - 101 Serious - US / Territories 2021. [online] Available at: https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=BF991AE0B02C34DC001DEED02ADB [Accessed 19 May 2022].

Spontaneous Abortion – BNT162b2 (Dec 2020- Dec 2021) USA

- 567 cases reporting Adverse Events of Spontaneous Abortion [Miscarriage], after receiving Pfizer BioNTech BNT162b2 vaccine; 472 entries identify Batch/Lot Numbers [VARES]*



* Accessed at http://wonder.cdc.gov/vaers.html on May 2, 2022 10:51:52 PM

3

What do the Batch/Lot Numbers tell us about a biologic such as BNT162b2? In the 567 cases that listed Spontaneous Abortion [Miscarriage], there were 471 with Batch/Lots, comprising 171 separate alphanumeric Batch/Lots. Six of the 171 Batch/Lots [approximately 14%] had significantly higher number of case counts: EP6955 (8), EK9231 (8), EW0168 (10), EN 6204(1), EK5730 (12), and ER8729 (17). Using https://howbad.info/, an on-line service of *The Exposé* that lists vaccine lot numbers linked with SAEs pulled from VAERS, I checked all six Batch/Lots and received a hit on EW0168: 10 ADRs, 8 Deaths, 20 Disabilities, 20 Life-threatening illnesses. (Exposé, 2022) In response to that finding, I decided to investigate based on the assumption that a sharper understanding will be achieved if a match can be made from *The Exposé* archive using all 171 Batch/Lot Numbers. The results are astonishing: 65 of the 171 [38.0%] returned results from *The Exposé* archive. The numbers breakdown: total number of serious adverse reactions [ADRs] = 32,051; Death = 400; Disabilities = 475; and Life- threatening illness = 413. See chart.

What is important is the dose (toxicity concentration) for each Batch/Lot Number, established at the plant, which must first pass review by the FDA before being sent to the distributor for release to the public. The one thing that links the patient outcome, the causal relationship, with the BioNTech

[BNT162b2] vaccine, is the Batch/Lot Number. This is the 'smoking gun.' If one knows this number, related characteristics (e.g., number of ADRs; Deaths, if any; Disabilities, if any; and Life-threatening illnesses, if any) and follow it, there is high probability of finding a patient who has or will succumb to its nefarious attributes.

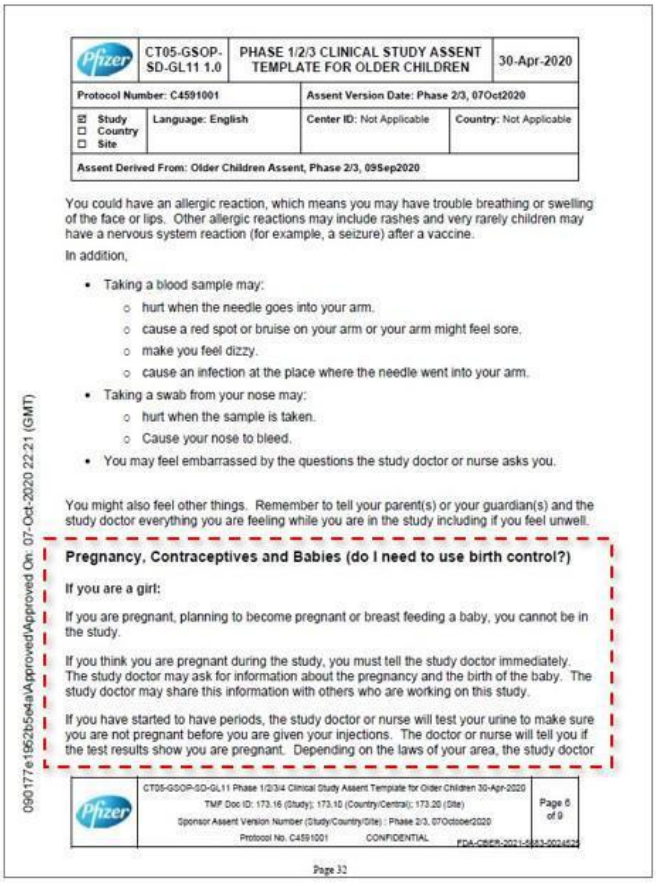
65 Batch/Lot Numbers Identified as Dangerous to Health of the Patient

Batch/Lot No.	ADRS	Death	Diasbilities	Life Threatening Illness
301308a	736	6	10	9
301358A	294	7	2	5
30135BA	458	10	5	2
30145BA	842	10	24	17
30155BA	501	7	10	3
3203080	20		1	
320308d	210	1	3	3
32030bd	282		3	3
33026BD	42			
330308D	41			
33030BD	39			
BNT162B2	59	3		1
ED7533	6			
EJI685	8			
EK4176	1092	10	15	7
EL 1284	99	1		1
EL9265	1302	13	15	19
EL9266	1254	23	19	22
EL9267	1249	21	18	18
EM6204	6			1
EM9810	1301	21	17	23
EN 6201	58		1	2
EN 6204	31			1
EN6209	17			2
EN9581	746	12	12	13
ENG203	11			1
Eng204	14			
ER 8735	44		1	
ER 8737	61	1		
er9735	6			
ES1686	11			
EW0165	301	2	6	2

Batch/Lot No.	ADRS	Death	Diasbilities	Life Threatening Illness
EW0168	1319	16	23	30
EW0183	1319	16	24	31
EW0198	1226	21	22	20
ew1058	21		1	
EWo182	36			
EWO196	34		2	
EWO198	46			1
EYO584	9			
F63527	17			
FA7484	920	11	12	7
FA7485	1230	14	18	11
FC3180	1246	16	16	15
FC3181	1164	18	21	11
FC3182	1029	21	18	10
FC3183	1230	21	20	12
FD0809	459	5	7	5
FD0810	58	1	2	2
FD8448	984	13	20	23
FE3592	853	15	11	10
FF2587	931	14	22	13
FF2588	744	11	9	14
ff2590	889	3	8	6
FF2593	659	6	10	4
FF8839	859	20	19	15
FF8841	1115	4	11	7
fg3527	430		4	3
FH8020	827	3	11	4
FH8027	328	2		1
FH8028	340		1	
fh8030	276			
FJ1620	187			
FJ8762	41			
Paa156051	84	1	1	3
Total	**32051**	**400**	**475**	**413**

The above findings beg the question: why was this data/information not reported earlier during the Pfizer BioNTech Phase 1/2/3 clinical trials? The simple answer is Pfizer BioNTech were aware of the side effects, especially those that were gender-related, long before human clinical trials. Proof of this insight is seen by the eligibility criteria used by Pfizer BioNTech-sponsored Phase 1/2/3 clinical trials perfectly aligning with the informed consent forms the patients agreed to, signed and dated.

Another illustration of those who control the data control the outcome is the eligibility criteria established in order to shape an expected favorable result and exclude those with the expected, unfavorable outcomes (e.g., Inclusion: "Women of childbearing potential (WOCBP) must have a negative beta-human chorionic gonadotropin urine test at Visit 0 and Visit 1; Male and Female, "agree to practice a highly effective form of contraception during the trial;" Exclusion Criteria, Females "Are breastfeeding on the day of Visit 0 or who plan to breastfeed during the trial, starting after Visit 0 and continuously until at least 90 days after receiving the last immunization").(*A Trial Investigating the Safety and Effects of Four BNT162 Vaccines Against COVID-2019 in Healthy and Immunocompromised Adults* - Full Text View - ClinicalTrials.gov, 2021) In addition, for clinical trials that contained adolescents, Pfizer produced a tailored Informed Consent that contained softened language that addressed the criteria. It contained statements excluding females from participation who were pregnant or breastfeeding. If included, females had to agree to blood draws to check for pregnancy before receiving a dose of the vaccine or placebo. If sexually active, they were informed to use contraceptives, and this was expected to be followed by the sexual partner, as well as signed and dated by the patients and their parent/guardian [citation, 125742_S1_M5_5351_c4591001-fa-interim-iec-irb-consent-form, pages 32-33].



CT05-GSOP-SD-GL11 1.0	PHASE 1/2/3 CLINICAL STUDY ASSENT TEMPLATE FOR OLDER CHILDREN	30-Apr-2020
Protocol Number: C4591001	Assent Version Date: Phase 2/3, 07Oct2020	
☑ Study ☐ Country ☐ Site	Language: English	Center ID: Not Applicable / Country: Not Applicable
Assent Derived From: Older Children Assent, Phase 2/3, 09Sep2020		

You could have an allergic reaction, which means you may have trouble breathing or swelling of the face or lips. Other allergic reactions may include rashes and very rarely children may have a nervous system reaction (for example, a seizure) after a vaccine.

In addition,

- Taking a blood sample may:
  - hurt when the needle goes into your arm.
  - cause a red spot or bruise on your arm or your arm might feel sore.
  - make you feel dizzy.
  - cause an infection at the place where the needle went into your arm.
- Taking a swab from your nose may:
  - hurt when the sample is taken.
  - Cause your nose to bleed.
- You may feel embarrassed by the questions the study doctor or nurse asks you.

You might also feel other things. Remember to tell your parent(s) or your guardian(s) and the study doctor everything you are feeling while you are in the study including if you feel unwell.

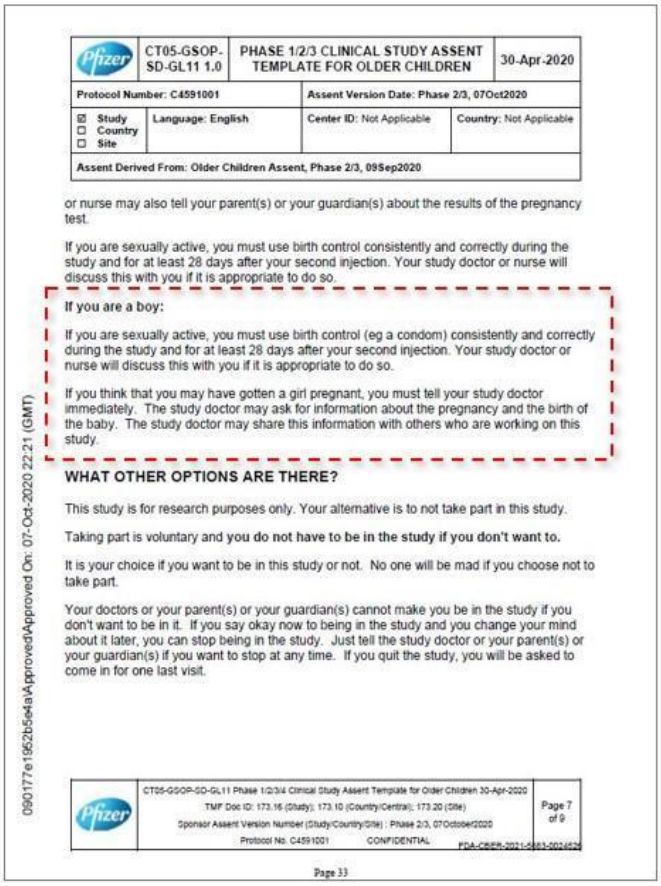
Pregnancy, Contraceptives and Babies (do I need to use birth control?)

If you are a girl:

If you are pregnant, planning to become pregnant or breast feeding a baby, you cannot be in the study.

If you think you are pregnant during the study, you must tell the study doctor immediately. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study.

If you have started to have periods, the study doctor or nurse will test your urine to make sure you are not pregnant before you are given your injections. The doctor or nurse will tell you if the test results show you are pregnant. Depending on the laws of your area, the study doctor



CT05-GSOP-SD-GL11 1.0	PHASE 1/2/3 CLINICAL STUDY ASSENT TEMPLATE FOR OLDER CHILDREN	30-Apr-2020
Protocol Number: C4591001	Assent Version Date: Phase 2/3, 07Oct2020	
☑ Study ☐ Country ☐ Site	Language: English	Center ID: Not Applicable / Country: Not Applicable
Assent Derived From: Older Children Assent, Phase 2/3, 09Sep2020		

or nurse may also tell your parent(s) or your guardian(s) about the results of the pregnancy test.

If you are sexually active, you must use birth control consistently and correctly during the study and for at least 28 days after your second injection. Your study doctor or nurse will discuss this with you if it is appropriate to do so.

If you are a boy:

If you are sexually active, you must use birth control (eg a condom) consistently and correctly during the study and for at least 28 days after your second injection. Your study doctor or nurse will discuss this with you if it is appropriate to do so.

If you think that you may have gotten a girl pregnant, you must tell your study doctor immediately. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study.

WHAT OTHER OPTIONS ARE THERE?

This study is for research purposes only. Your alternative is to not take part in this study.

Taking part is voluntary and **you do not have to be in the study if you don't want to.**

It is your choice if you want to be in this study or not. No one will be mad if you choose not to take part.

Your doctors or your parent(s) or your guardian(s) cannot make you be in the study if you don't want to be in it. If you say okay now to being in the study and you change your mind about it later, you can stop being in the study. Just tell the study doctor or your parent(s) or your guardian(s) if you want to stop at any time. If you quit the study, you will be asked to come in for one last visit.

In closing, I have offered some insight into various red flags associated with AE and SAE or events, as well as the attempted controls of the data thereof, which answer why Pfizer wanted to keep this information 'confidential' for 75 years and blocked from scientists capable of an independent peer review, long after those complicit in the scheme and the scientist most familiar with the matter would be dead. Everything one needs to know that is wrong about the corporate/government dystopian partnership of Pfizer Inc. and United States Food and Drug Administration (USFDA) can be summed up by Mr. Aaron Siri (Siri & Glimstad LLP). This is the firm that filed the brief that led to FOIA that ultimately forced the FDA rollout of the Pfizer vaccine 'confidential' documents. Siri said, "Decoupling a company's profit interest from its interest in safety is a moral hazard, and a departure from centuries of product liability doctrine," [PHMPT vs. FDA, Brief in Support of Timely Production, page 2].

Report 29: "Pfizer's New Two-in-One COVID-19 Booster: Are We the Clinical Trial?" by Linnea Wahl, MS – Team 5.

The Pfizer booster vaccine that people get this fall may have some surprises. The fall 2022 booster will be formulated to respond to two different strains of SARS-CoV-2, one of which is already extinct and the other, an Omicron variant, will surely be in decline by fall. And this fall's Pfizer "bivalent" – i.e., "conferring immunity to two diseases" [Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/bivalent] – booster may be formulated to deliver twice the amount of mRNA than previous Pfizer shots. All with no clinical trials completed. Will the next Pfizer booster have as many (or more) serious side effects as the current vaccine?

On June 30, 2022, the US Food and Drug Agency issued recommendations to vaccine manufacturers for their fall 2022 vaccination campaign. [https://www.fda.gov/media/159597/download] Their recommendation: develop a two-component, or bivalent, COVID-19 booster vaccine that contains mRNA to produce spike protein from both the original virus and from the Omicron strains currently circulating in the United States.

Pfizer seems to have anticipated the FDA's recommendation, as Pfizer has already begun developing bivalent booster vaccines.[https://www.fda.gov/media/159496/download] One bivalent booster vaccine that Pfizer is developing will deliver a total dose of 30 micrograms (the same total dose as the original vaccines and boosters): 15 micrograms of the original vaccine and 15 micrograms of Omicron variant vaccine. Will they be safe? Not if the safety findings for Pfizer's original 30-microgram vaccines, as reported by DailyClout analysts, hold true. [https://dailyclout.io/category/campaigns/pfizer-documents-analysis/]

Another bivalent booster vaccine that Pfizer is developing will deliver a total dose of 60 micrograms (twice the total dose as the original vaccines and boosters). This high-dose bivalent booster vaccine will provide 30 micrograms of the original vaccine and 30 micrograms of Omicron variant vaccine—twice the amount that has already resulted in increased risk of serious side effects. [https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239]

If Pfizer continues with a 60-microgram bivalent booster vaccine, will it be safe? We know that Walsh et al (2020) reported on Pfizer's clinical studies of doses of 10, 20, 30, and 100 micrograms of the original mRNA vaccine. [https://www.nejm.org/doi/full/10.1056/NEJMoa2027906] We know that Pfizer chose the 30-microgram dose because the "immune response and toxicity profile at the selected, relatively low, 30-microgram dose level indicate . . . a favorable balance of reactogenicity [side effects] and immunogenicity [viral protection]" (Walsh et al., p.11). And we know that Pfizer suddenly stopped the clinical study of the 100-microgram dose in 12 participants early, noting that "the second dose was not administered because of reactogenicity [side effects] in the participants . .

." (Walsh et al., p. 7). What we don't know is how many serious side effects will result from a 60-microgram dose of mRNA bivalent booster vaccine.

Nor do we know *why* the FDA has recommended booster vaccines that target both the original virus and the Omicron strains currently circulating in the United States. By the FDA's own admission, "there is no evidence to suggest that earlier strains of virus such as the original prototype strain represented in current vaccines . . . are in existence" (https://www.fda.gov/media/159597/download, p. 5). Why would the FDA recommend that bivalent booster vaccines continue to target the original virus strain, which is already extinct?

Additionally, Pfizer has demonstrated to the FDA that Omicron strains circulating in the United States have a history of changing quickly, within a matter of a few months. [https://www.fda.gov/media/159496/download] As shown in Pfizer's chart (Fig. 1), the currently circulating Omicron strains will probably already be in decline or extinct, like the original strain, when Pfizer introduces its bivalent booster vaccines this fall.

In making their recommendations for COVID-19 mRNA bivalent booster vaccines, the FDA is proposing to adopt the same approach it uses for updating seasonal influenza vaccines. This approach involves choosing which strains of influenza will dominate the next flu season and then modifying existing influenza vaccines to target those strains. And this approach works (with an effectiveness of 10 to 60%) for influenza in part because influenza is predictable—it strikes in the fall everywhere around the world. [https://www.cdc.gov/flu/vaccines-work/effectiveness-studies.htm] But by the FDA's own admission, "SARS-CoV-2 variants have not appeared in a predictable seasonal pattern and have not always spread globally" (https://www.fda.gov/media/157466/download, p. 9).

So, will the approach to seasonal influenza vaccines be safe and effective if it is applied to developing bivalent booster vaccines for COVID-19? Not if Pfizer's own clinical trials with two versions of its vaccine, with different mRNA sequences, is any indication. Researchers determined that one mRNA version caused too many side effects, noting that "the nucleotide composition of RNA has been reported to affect its immune stimulatory activity and reactogenicity profile . . ." (Walsh et al., p. 11). What unknown or variable physiological side effects can we expect from Pfizer's modified mRNA bivalent booster vaccines?

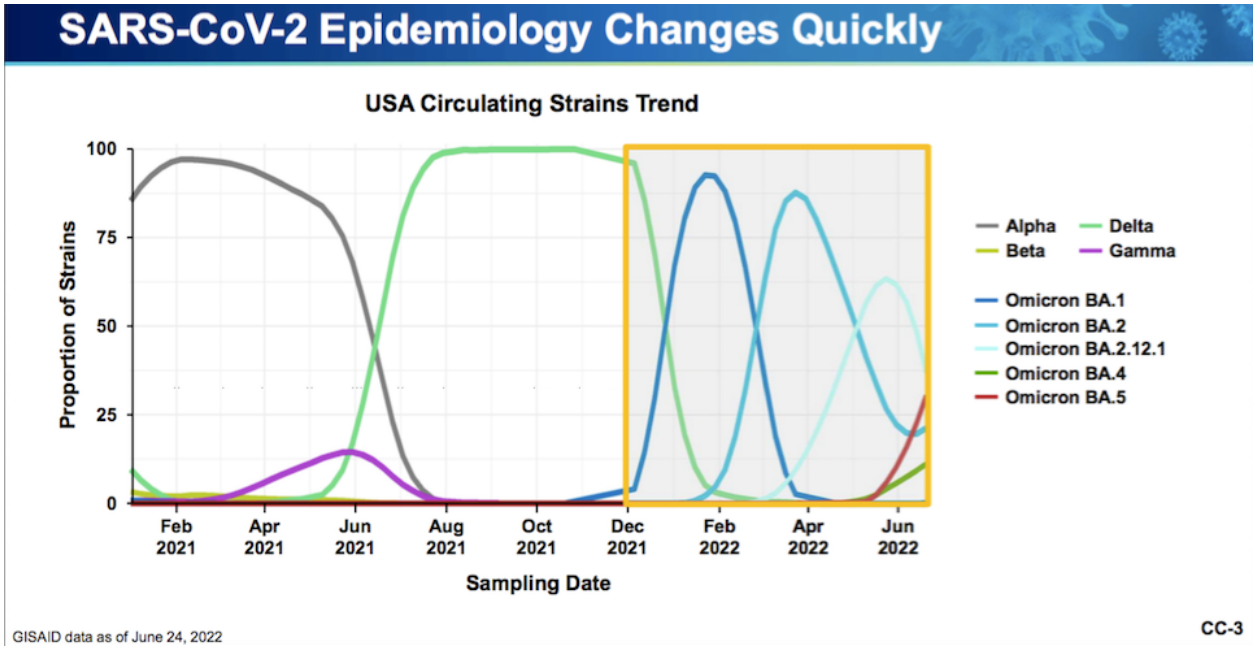
Sadly, we won't know the answers to important questions about this fall's bivalent booster vaccines until well after they are available to the public. The FDA has asked manufacturers to *begin* clinical trials with bivalent booster vaccines, but clinical trials take time, and results of these trials will not be available before the FDA's expected rollout in fall 2022.[https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-recommends-inclusion-omicron-ba45-component-covid-19-vaccine-booster] Instead, the FDA is content "to rely on comparative

immunogenicity data due to the time constraints involved in vaccine manufacturing and clinical efficacy evaluation." [https://www.fda.gov/media/159597/download, p. 7]

Pfizer's new bivalent booster vaccines: are they safe and effective? We will know eventually, but certainly not before the bivalent booster vaccines are in wide use. Are we, the public, going to be Pfizer's experimental population, yet again?

Fig. 1 SARS-CoV-2 Epidemiology Changes Quickly

Source: Pfizer/BioNTech COVID-19 Vaccine and Candidate Variant-modified Vaccine, FDA Vaccines and Related Biological Products Advisory Committee, June 28, 2022, https://www.fda.gov/media/159496/download.



Report 30: "Understanding C-19 Vaccine Efficacy Clinical Trial in Lay Terms" by Melanie Brown – Team 4.

The Moderna vaccine decreases the production of antibodies to the nucleocapsid in a dose dependent fashion in those who acquire COVID after vaccination.

Four months after injection, **40% of vaccinated participants who acquired COVID after the second injection produced antibodies to the nucleocapsid**, compared to 93% of those who received placebo injections.

In participants that were COVID positive on the day of Dose 1 injections (before the vaccinations had time to work) a robust production of anti-nucleocapsid antibodies occurred in both placebo and vaccinated groups, with no difference between the groups. In the participants that acquired COVID between doses, a reduction in anti-nucleocapsid antibodies was observed in those who received the vaccine compared to those who received placebo. The reduction was not as severe as the group who acquired COVID after the second dose. Thus, **it appears the more doses received, the more severe the reduction in anti-nucleocapsid antibody production.**

Moderna vaccination in people that have never had COVID previously reduces the production of anti-nucleocapsid antibodies compared to placebo. This may reduce the strength and duration of immunity to COVID compared to unvaccinated immune responses. The more doses, the less the production of anti-nucleocapsid antibodies.

Further investigation is warranted with all COVID vaccine types in larger populations, to determine if this phenomenon is observed in all COVID vaccine products, because they all use the spike protein mRNA. This would include Pfizer/BioNTech, Jannsen, AstraZeneca and Novavax. Also, it is important to determine the relative effectiveness of the anti-nucleocapsid antibodies versus the anti-spike antibodies against COVID and its variants.

If the mRNA vaccines decrease the production of anti-nucleocapsid antibodies in a dose dependent fashion, immunity would be short-lived and possibly lessened with additional boosters, the opposite of the desired outcome. This decreased immunity would affect all vaccinated people who had no COVID previous to their vaccination.

A nested sub-study was performed on participants that got COVID during the blinded phase in Moderna's Phase 3 clinical trial for the mRNA-1273 COVID vaccine. The purpose of this nested study was to determine if vaccinated people produce or maintain the anti-N ab at the same level as those who are not vaccinated after getting COVID. The sub-study was discussed in medRxiv, "Anti-nucleocapsid antibodies following SARS-CoV-2 infection in the blinded phase of the mRNA-1273

Covid-19 vaccine efficacy clinical trial" by Follmann, D., Janes, H.E., et al. [https://doi.org/10.1101/2022.04.18.22271936]

This study compared the production of antibodies (from the viral nucleocapsid) in participants that received placebo to those who received the vaccine.

*A **nucleocapsid** is a protein that envelops the viral genetic material for its protection. In contrast, the **spike proteins** protrude out from the nucleocapsid and are responsible for the virus being able to enter human cells to cause COVID.*

*The antibodies against this nucleocapsid are abbreviated as "**anti-N Ab**."*

*The antibodies to the spike protein are abbreviated as "**anti-S Ab**."*

*For simplicity, this summary will just use the term "**vaccine**" when discussing the Moderna mRNA-1273 COVID vaccine. SARS-CoV-2 is the name of the virus that causes COVID.*

*The **blinded phase** of a clinical trial is the portion in which the participants did not know if they received placebo or vaccine.*

Briefly, the blinded portion of the Phase 3 clinical trial design consisted of two groups: those receiving two doses of placebo, and those receiving two doses of the vaccine, 28 days apart. Treatments were given on Day 1 and Day 29, and participants were followed for approximately four months, at which time they were told which treatment they received, and the trial was, thus, unblinded. This time point was called the "Participant Decision Visit" or "PDV." The nested portion included COVID tests taken from all participants on Day 1, Day 29, and during any symptom-prompted illness visits to diagnose COVID infection. Serum samples from Days 1, 29, 57, and the PDV were tested for anti-N Ab levels by immunoassay.

The Results

Table 1 shows positive anti-N ab tests at the PDV for participants with COVID detected at an illness visit during the study. These participants had no previous COVID illness prior to the study so therefore acquired it during the study. A substantial difference in anti-N ab production was shown between groups: 40.4 percent (21/52) in vaccine recipient COVID cases versus 93.3 percent (605/648) in placebo-recipient COVID cases. Thirty-six of the 52 vaccine recipients also had anti-S ab levels measured. Twenty of them were anti-N ab negative, and 16 of them were anti-N ab positive. Among these 36 individuals, the anti-S ab titers were not significantly different between those who were anti-N ab negative or those who were anti-N ab positive. **This indicates that the vaccine did not negatively impact the level of the anti-S ab as it did with the anti-N Ab.** Not

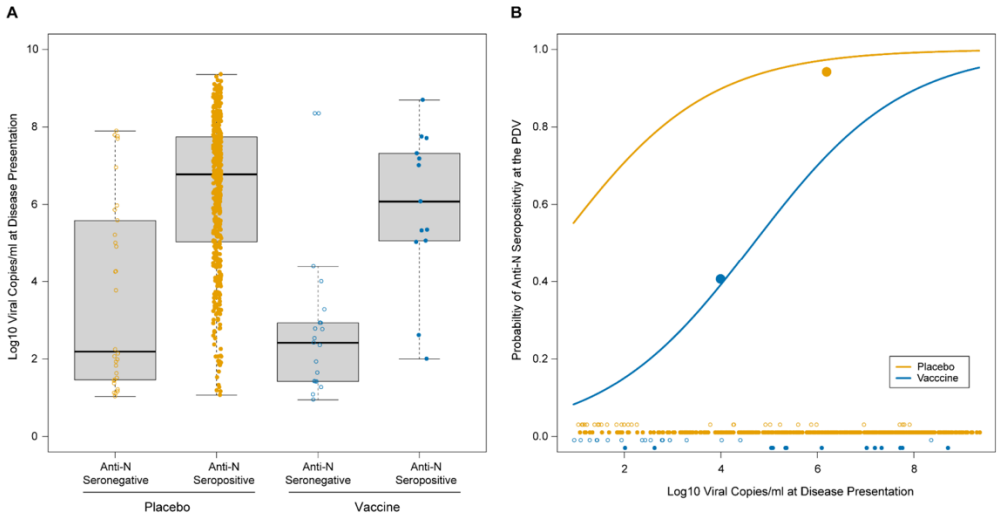
surprising, considering that the vaccine causes the body to produce the spike protein only, without a nucleocapsid. It makes sense that vaccinated individuals would have robust anti-S ab production due to large amounts of the spike protein present.

Table 1. Anti-N seropositivity rates at the PDV for those who acquired disease at least 14 days post dose 2 and were seronegative and PCR negative at baseline (primary endpoint Covid-19 cases): Full Analysis Set Population.

	Placebo		mRNA-1273	
Days from Disease to PDV	**N**	**% Anti-N Seropositivity (95% CI)**	**N**	**% Anti-N Seropositivity (95% CI)**
5-150 days	648	93.4% (91.5%, 95.3%)	52	40.4% (27.1%, 53.7%)
5-53 days	324	93.8% (91.2%, 96.4%)	28	32.1% (14.8%, 49.4%)
54-150 days	324	92.9% (90.1%, 95.7%)	24	50.0% (30.0%, 70.0%)

COVID viral loads were also measured and compared (Figure 1). The viral load at the illness visit was significantly higher in placebo recipients who were positive for anti-N Ab on the PDV (6.8 log10 copies/ml) than in placebo recipients who were negative for anti-N Ab on the PDV (2.2 log10 copies/ml). It makes sense that the higher the viral load an individual has, a greater number of antibodies would be generated. Similar results were seen in the vaccine group (6.1 log10 copies/ml for anti-N ab positive individuals and 2.4 log10 copies/ml for anti-N ab negative individuals). Thus, **the viral load does not offer much insight into the difference in anti-N ab positivity at the PDV between the placebo and vaccinated groups that got COVID during the clinical trial.**

Figure 1



These data show that, among the participants with PCR-confirmed COVID, anti-N Ab positivity about 53 days post diagnosis occurred in 40% of the vaccine recipients vs. 93% of the placebo recipients. Though it is possible the vaccine caused a loss of anti-N ab, given the short time frame it is more likely that the vaccine reduced the production of the anti-N ab.

A comparison was made of 'anti-N ab levels per viral load' in study participants that were ill on Day 1 to the 'average anti-N ab level per viral load' over all illness visits. This comparison showed the virus reproducing at Day 1 illness more than at other time points in the study, meaning that at Day 1 (before the vaccinations had time to work) more anti-N ab was produced in response to the magnitude of the viral load.

Comparison of placebo versus vaccinated recipients with COVID detected at baseline showed similar anti-N ab production rates at both Day 29 and PDV for both groups (Table 2). These robust ab titers were also maintained through the PDV for both groups, which **indicates that actual infection before vaccination created robust anti-N ab titers that were long-lasting. Table 2**

Table 2. Anti-N seropositivity rates at Day 29 and PDV for infections detected by serology or PCR at Day 1 (Baseline).

	Anti-N Serostatus at Day 29				**Anti-N serostatus at PDV**				
	Placebo		**mRNA**		**Placebo**		**mRNA**		
Infection Detection	**N**	**% Positive (95% CI)**	**N**	**% Positive (95% CI)**	**N**	**% Positive (95% CI)**	**N**	**% Positive (95% CI)**	**Median Days (IQR)**
Baseline Seropositive	284	95.1% (92.6%, 97.6%)	281	96.1% (93.8%, 98.4%)	244	94.3% (91.4%, 97.2%)	260	93.8% (90.9%, 96.7%)	149.0 (76.0-236.0)
Baseline PCR+*	27	74.1% (57.6%, 90.6%)	30	73.3% (57.5%, 89.1%)	23	82.6% (67.1%, 98.1%)	31	71.0% (55.0%, 87.0%)	153.5 (86.0-220.0)

*Also baseline seronegative.

Comparison of participants from both groups that became ill at Day 29 and were anti-N ab positive, showed no difference between placebo and vaccinated groups at day 57 and at PDV. For those participants that were anti-N ab negative but had a positive PCR test for COVID on Day 29, the positivity rates are 60.0 percent (18/30) for the placebo group and 38.5 percent (5/13) for the vaccinated group at Day 57 and 70.4 percent (19/27) and 50.0 percent (6/12), respectively at the PDV. Consistent with the effects seen among baseline infections, the Day 57 and PDV anti-N ab positivity rates are significantly lower for Day 29 PCR-positive. Anti-N ab-negative participants were also compared to Day 29 anti-N ab-positive participants in both groups, but the vaccinated group was significantly lower than the placebo group. This indicates that **even one vaccine on board seems to depress the anti-N antibody production**, though not as severely, suggesting that **the more vaccinations taken the greater the reduction in anti-N ab production.**

Table 3. Anti-N seropositivity rates at Day 57 and PDV for infections detected by serology or PCR at Day 29 (dose 2).

	Anti-N Serostatus at Day 57				Anti-N serostatus at PDV				
	Placebo		mRNA		Placebo		mRNA		
	N	% Positive (95% CI)	N	% Positive (95% CI)	N	% Positive (95% CI)	N	% Positive (95% CI)	Median Days (IQR)
New Seropositive Day 29*	61	86.9% (78.4%, 95.4%)	39	84.6% (73.3%, 95.9%)	51	84.3% (74.3%, 94.3%)	36	86.1% (74.8%, 97.4%)	118.0 (61.0-189.0)
New PCR+ Day 29**	30	60.0% (42.5%, 77.5%)	13	38.5% (12.0%, 65.0%)	27	70.4% (53.2%, 87.6%)	12	50.0% (21.7%, 78.3%)	112.0 (49.0-168.0)

*Also baseline seronegative and baseline PCR negative.
**Also baseline and Day 29 seronegative, and baseline PCR negative.

This data shows that, **among the participants with COVID, anti-N Ab production occurred in 40 percent of the vaccine recipients versus 93 percent of the placebo recipients.** While an increase in the loss of these antibodies cannot be ruled out, given the short time frame, the more likely explanation is a vaccine-induced reduction in production of them. Anti-N ab production correlated with viral load, with each log increase in viral load nearly doubling the odds of anti-N ab production at the PDV. These lower anti-N ab titers in the vaccine recipients could be partly explained by their reduced exposure to the nucleocapsid antigen and/or overwhelming spike protein exposure. Alternatively, it could be explained by a combination of these. There may be other features of the initial course of infection that influence anti-N Ab production and are affected by vaccination. **The average viral load across post-COVID illness visits did not correlate or influence anti-N ab titers at PDV**.

The authors of the original article were more concerned with determining a population's prevalence and incidence of past COVID infections while using the anti-N ab titer. However, this author thinks the main takeaway is that **vaccination with the Moderna vaccine actually reduces the production of anti-N ab compared to placebo and, thus, may reduce the strength and duration of immunity toward COVID compared to unvaccinated immune responses.** This phenomenon increases with the number of vaccinations received. The sub study authors believe that the anti-S abs alone provide enough immune protection, which in the short-term may be true since 648 placebo recipients fell ill during the study compared to 52 vaccine recipients. This was a very short time period that was studied, only four months. Natural immunity after getting a disease often protects for a lifetime.

Statistics do not support long-lasting immunity for the COVID vaccines since many **more vaccinated people are getting COVID than unvaccinated** (Mercola, J., May 25, 2022, "Is this the worst excuse for vaccine failure yet?," Z3News). This remains true even with people receiving up to three or four vaccinations. Another paper published online discusses this as well (Eur J Epidemiol. 2021; 36(12): 1237–1240. "Increases in COVID-19 are unrelated to levels of vaccination

across 68 countries and 2947 counties in the United States." Subramanian, SV and Kumar, A. Published online 2021 Sep 30).
Finally, this article [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/] from National Library of Medicine shows **the higher the vaccination rate in a country, the higher the number of COVID cases**; and countries with lower vaccination rates have lower numbers of COVID cases.
In conclusion, **the immunity provided by the vaccines is short-lived, and it could partially be explained by the lack of anti-N ab production after vaccination.**

Report 31: "Pfizer Evidence So Far: Coverups, Heart Damage, and More" by Robert W. Chandler, MD, MBA, and Linnea Wahl, MS – Team 5.

Less than three months after Pfizer's COVID-19 vaccine rollout, there were many known **significant adverse events (AEs).** So many, in fact, that **Pfizer had to hire 2,400 employees to handle the volume reports they were receiving**. Despite the flood of adverse events being reported, **there was no move** by Pfizer, the U.S. government, or government entities such as the CDC or FDA **to stop or slow down the rollout of the mRNA vaccines.**

At least four or more appendixes may have been omitted from this report. [https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf] There has also been some modification of the primary source document:

- Pericarditis and myocarditis are included in the cardiac (heart-related) organ system rather than under autoimmune disorders. Adverse events of special interest (AESIs) are organized as organ systems.
- 1,972 cases of Lymphadenopathy (swelling of lymph nodes) appear with no reporting of low white blood cell count (lymphocytopenia) or other measurements of infection or dysfunction including the formation of cancers.
- Absence in the reporting of Troponin and d-dimer (protein fragment present in the blood after a blood clot) levels. Without the raw data, we have no way of knowing just how high d-dimer levels were. **This is significant because of the correlation between high d-dimer levels and blood clots.**

Following the granting of Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) in late fall of 2020, Pfizer, with assistance from private and government agencies, began widespread "vaccination" of the public. The following report is a series of tables and charts meant to make access to data contained in primary source document *5.3.6 Reissue* more transparent.

"Relevant" Adverse Events:
Subjects

Table 1	N =	42086	
Gender	F	29914	71%
	M	9182	22%
	ND	2990	7%
	Total	42086	
<12	**34**		
<16	**46**		
<= 17	**95**		
Age			
	18-30	4953	
	31-50	13886	
	51-64	7884	
	65-74	3098	
	>=75	5214	
	Ukn	**6876**	
	Total	**42086**	
Outcome	N =	42086	
*Of (total)-(unknown)	Recovered/Recovering*	19582	60%
*Of (total)-(unknown)	Not recovered*	11361	35%
Of 42,086	**Unknown***	**9400**	22%
	Fatal*	**1223**	4%
Of (total)-(unknown)	Recovered with sequelae*	520	2%
N - Unknown =	**32686**		

Estimated range in all cases not recovered after removing unknowns	**Died or not Recovered**	**40-87%**

Percent recovered to percent not recovered	Recovered 17624	Not Recovered 1958
9 to 1		
6 to 4	11749	7833
5 to 5	9791	9791
4 to 6	7833	11749
1 to 9	4209	15373

Recovered/Recovering Estimation Calculations	**Estimated Not Recovered + Died**	**Estimated percent not recovered**
Fatal + Not recovered + Sequelae	13104	40%
Fatal + NR + S + estimated recovering*	15062	46%
* Scaled estimated Recovering	20937	64%
	22895	70%
	24853	76%
	28477	87%

Table 1 Disorders >= 2%	**WHERE IS THIS DATA?**		
General and admin site	**51335**	122%	Compare with 42086
Nervous System	**25957**	62%	
MS & Connective Tissue	**17283**	41%	
GI	**14096**	33%	
Resp, Thoracic, and Mediastinal Skin and SubCu	**8848**	21%	
Injury, poisoning, and procedural	**8476**	20%	
	5590	13%	**WHERE IS THIS TOXICITY DATA?**
Covid-19	**1927**	5%	
Investigations	**3693**	**9%**	**????**
Total	**137205**	**93473**	**????**

Table 2 Events >=2% Cases N = 42086

	Blood and lymphatic	1972	4.69%
	Cardiac Table 2	1098	"Tachycardia"
	Cardiac Table 7	1403	Table 2 + 7
	Auto immune Myocarditis	25	
	Auto immune Pericarditis	32	
	Total Cardiac	1460	3.47%
	GI	8760	20.81%
	General and admin site	39451	93.74%
See total from Table 7	**COVID19**	**1927**	**4.58%**
Total procedural errors	**Procedural complications**	**1708**	**4.06%**
3416	**Off label use**	**880**	**2.09%**
	Product use issue	**828**	**1.97%**
	Musculoskeletal & CT	12399	29.46%
	Nervous system	16350	38.85%
	Respiratory, Thoracic, Mediastinal	4151	9.86%
	Skin and SubQ	5657	13.44%
	Total number of events	**93473**	**2.2 per subject**

Table 3-5 Safety Concerns	Cases	
Anaphylaxis BC1-4	**1002**	**4 patients died on the same day the injection was given**

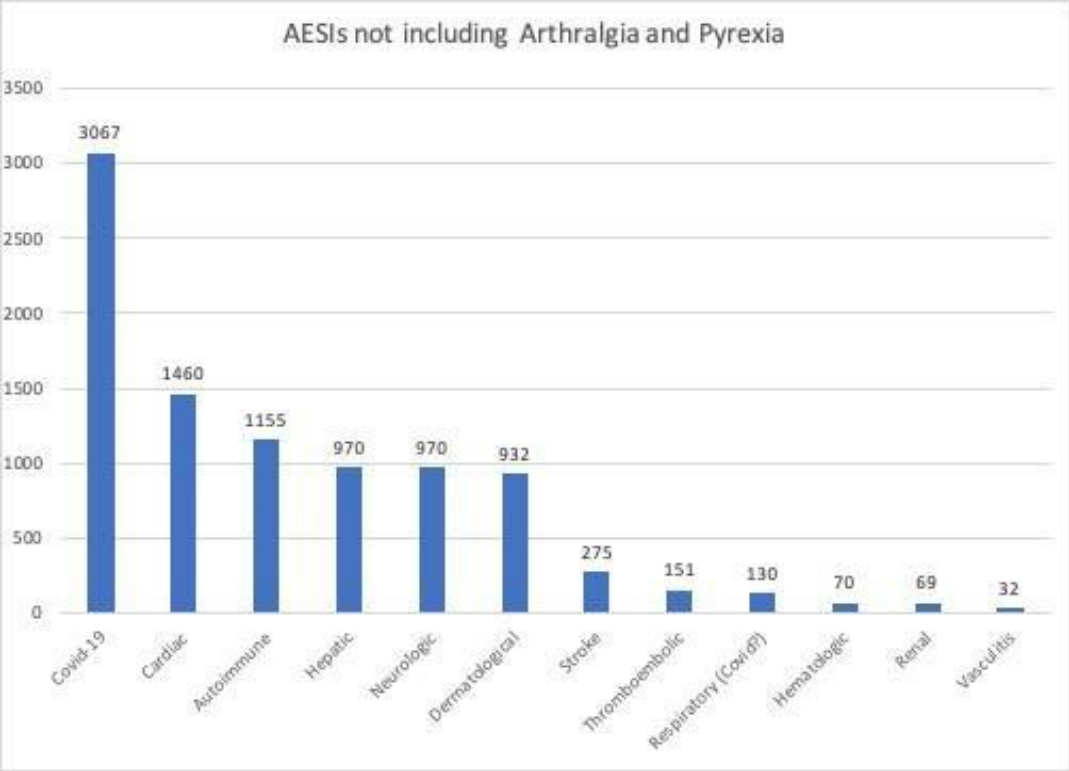
Potential Anaphylaxis Cases	2958	9.4%
Vaccine Enhanced Disease	138	317 events
Use in Pregnancy and Lactation	413	84 S/329 NS
Pregnancy outcomes	N = 270	
No Outcome	**238**	**88%**
Outcome Pending	5	
Known outcome	**27**	
Spontaneous abortions	**23**	**85%**
Premature birth neonatal death	2	7%
Spontaneous abortion intrauterine death	2	7%
Spontaneous abortion neonatal death	1	4%
Normal outcome	**1**	**4%**
Mother cases	124	
Spontaneous abortion	25	20%
Myalgia	16	13%
Pyrexia	16	13%
Lymphadenopathy	7	6%
Chest pain	6	5%
Dizziness	6	5%
Asthenia	6	5%
Malaise	5	4%
Covid-19	5	4%
Uterine contraction	1	1%
Premature membrane rupture	1	1%
Abortion	1	1%
Abortion missed	1	1%
Fetal death	1	1%
Serious fetus/baby cases	4	
Fetal growth restriction/premature baby	2 each	
Neonatal death	1	

Breast feeding baby cases	133	
No adverse events	116	87%
Breast feeding infant child reactions of those with AEs	17	13%
Fever	5	29%
Rash	4	24%
Irritability	3	18%
Vomiting	2	12%
Diarrhea	2	12%
Insomnia	2	12%
Illness	2	12%
Poor feeding	1	6%
Lethargy	1	6%
Abdominal discomfort	1	6%
Vomiting	1	6%
Allergy to vaccine	1	6%
Increased appetite	1	6%
Anxiety	1	6%
Crying	1	6%
Poor quality sleep	1	6%
Eructation	1	6%
Agitation	1	6%
Pain	1	6%
Urticaria	1	6%
Breast feeding mother cases	6	
Chills, malaise, and pyrexia	1	
Suppressed lactation	4	
Unknown AE	1	
Breast milk discoloration	1	

Pediatric age <12	**34**	**132 AEs**
Age range (Youngest 28 days not 2 months)	**2 mos. to 9 years**	**3.7 years average**
Serious	24	71%
Non-serious	10	29%
Product administered to Pt of inappropriate age	27	**1 seven-year-old had a stroke**
Off label use	11	
Pyrexia	6	
Product use issue	5	
Fatigue	4	
Headache	4	
Nausea	4	
Injection site pain	3	
Abdominal pain	2	
COVID-19	2	
Facial paralysis	2	
Lymphadenopathy	2	
Malaise	2	
Pruritis	2	
Swelling	2	

"Vaccine" effectiveness	Table 6		
Failure	19	7 days after two doses	Confirmed C19
"Vaccine" ineffective	1649	Unknown: 2 doses?, # days since 1st dose, unk. time since 2nd.	Suspected C19
COVID-19	3067		
Outcome unknown	1230	74%	
Fatality	65	15%	

From Table 7 Analysis



COVID is the leading adverse event after arthralgia and fever

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

"Relevant" Adverse Events: Subjects	N = 42086	
Autoimmune (# and % of AEs)	**1155**	**3%**
Gender	**838**	
Female	682	
Male	156	
Age	**944**	
12-17	2	
18-64	746	
>=65	196	
Diagnoses	**855**	
Hypersensitivity	596	
Arthritis*	70	***From Musculoskeletal**
Peripheral neuropathy	49	
Rheumatoid arthritis*	26	***From Musculoskeletal**
Dermatitis	24	
Encephalitis	16	
Diabetes	16	
Psoriasis	14	
Bullous dermatitis	13	
Autoimmune disorder	11	
Reynaud's phenomenon	11	
Polyarthritis*	5	***From Musculoskeletal**
Polyneuropathy*	4	***From Musculoskeletal**

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	N = 42,086	
Outcome	**1078**		
Other	517		
Unknown	**312**		**28.9%**
Not resolved	215		
Resolved with sequelae	**22**		**2.0%**
Fatal	**12**		**1.1%**
	AEs	N =	
Cardiac (# and % of AEs)	**1460**		**3.5%**
Gender	**1403**		
Female	1076		
Male	291		
Unknown	36		
Age	**1346**		
2-11	**1**		
12-17	**1**		
18-64	**1078**		
>= 65	266		

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	N = 42,086	
Diagnoses	**1498**		
Arrhythmia [1]	1200		
Myocardial Infarction	130		
Cardiac Failure	91		
Pericarditis*	**32**		**From Autoimmune**
Myocarditis*	**25**		**From Autoimmune**
Cardiogenic shock	7		
Postural orthostatic tachycardia syndrome	7		
Coronary artery disease	6		
[1] 7666 subjects had "pyrexia". Fever is accompanied by elevation in heart rate 10 beats/min for females per degree C and 7 b/m for males per degree C.	**Assuming tachycardia listed in Table 7 refers to SVT etc.**		
Outcome	**1444**		
Other	767		
Unknown	**380**		**26.0%**
Not resolved	140		
Fatal*	**136**		**9.3%**
Resolved with Sequelae	21		
***May not include Myopericarditis fatalities**			

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	N = 42,086	
COVID-19 (# and % of total AEs)	**3067**	**7.3%**	
Gender	**3067**		
Female	1650		
Male	844		
Unknown	573		
Age	**1880**		
Infant*	**2**		***28 days to 27 mos.**
2-11	**1**		
12-17	**2**		
18-64	1315		
>= 65	560		
Diagnoses	**3356**		
COVID-19	1927		
SC2 test +	415		
Suspected C19	270		
Ageusia	228		
Anosmia	194		
SC2 Antibody test negative	83		
Exposure to SC2	62		
SC 2 Antibody test positive	53		
C 19 pneumonia	51		
Asymptomatic C19	31		
Coronavirus infection	13		
Occupational exposure SC2	11		
SC2 false positive test	7		
SC2 test positive	6		

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	N = 42,086
SC 2 test negative	3	
SC 2 antibody test negative	2	
Outcome	**3360**	
Unknown	**2110**	**62.8%**
Other	558	
Fatal	**136**	**4.0%**
Resolved with sequelae	**9**	
Not resolved	547	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	N = 42086
Dermatological (# and % of total AEs)	**20**	0.05%
Gender	19	
Female	17	
Male	1	
Unknown	1	
Age	19	
Infant	0	
2-11	0	
12-17	0	
18-64	18	
>= 65	1	
Diagnoses	20	
Erythema multiforme	13	
Vasculitis	7	
Outcome	21	
Not resolved	8	
Other	7	
Unknown	**6**	**29%**

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021
Table 7: Adverse Events of Special Interest

	AEs	N = 42,086
Hematological (# and % of Total AEs)	**932**	
Gender	898	**Bleeding**
Female	676	**731**
Male	222	**87%**
Unknown	N/A	
Age	**837**	
Infant	1	
2-11	0	
12-17	0	
18-64	543	
>= 65	293	
Diagnoses	888	
Epistaxis	127	
Contusion	112	
Site bruising	96	
Site hemorrhage	51	
Petechiae	50	
Hemorrhage	42	
Hematochezia	34	
Thrombocytopenia	33	
Site hematoma	32	
Conjunctival hemorrhage	29	
Vaginal bleeding	29	
Hematoma	27	
Hemoptysis	27	
Menorrhagia	27	
Hematemesis	25	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	N = 42,086	
Eye hemorrhage	23		
Rectal hemorrhage	22		
Immune thrombocytopenia	20		
Hematuria	35		
Neutropenia	16		
Purpura	16		
Hemorrhagic diarrhea	15		
Outcome	**1082**		
Other	393		
Unknown	**371**		**34%**
Not resolved	267		
Fatal	**34**		**3.1%**
Resolved with sequelae	17		

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021
Table 7: Adverse Events of Special Interest

	AEs	N = 42,086
Hepatic (# and % of Total AEs)	**70**	
Gender	**70**	
Female	43	
Male	26	
Unknown	1	
Age	**64**	
Infant	0	
2-11	0	
12-17	0	
18-64	37	
>= 65	27	
Diagnoses	82	
LFTs elevated	70	
Hepatic pain	9	
Ascites	3	
Outcome	**94**	
Unknown	**47**	
Other	27	
Not resolved	14	
Fatal	**5**	
Resolved with sequelae	1	

	AEs	N = 42086
Musculoskeletal (# and % of total AEs)	3495	**(-)Arthritis/polyneuropathy**
Gender	3471	
Female	2760	
Male	711	
Age	3372	
Infant	1	
2-11	4	
Arthralgia	**2**	
18-64	2850	
>= 65	515	
Diagnoses	3534	
Arthralgia	3525	
Post viral fatigue syndrome	4	
Chronic fatigue syndrome	4	
Bacterial arthritis	1	
Outcome	3662	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	N = 42,086
Other	1801	
Not resolved	959	
Unknown	853	
Resolved with sequelae	49	

Neurological AESIs (# and % of total AEs)	**950**	
Gender	927	
Female	623	
Male	283	
Unknown	21	
Age	**889**	
Infant	**1**	VIIth nerve palsy
2-11	**1**	
12-17	0	
18-64	642	
>= 65	245	
Diagnoses		
Facial paralysis	**401**	**Facial Nerve Injury =**
Seizure	204	**492**
Epilepsy	83	**Seizure =**
Facial paresis	**64**	**404**
Generalized seizure	33	**Demyelinating =**
Guillain-Barre syndrome	24	**28**
Fibromyalgia	17	**GB =**
Trigeminal neuralgia	**17**	**24**
Febrile convulsion	15	
Status epilepticus	12	
Aura (petit mal?)	11	
Transverse myelitis	11	
Multiple sclerosis relapse	10	
Optic neuritis	10	
Petit mal epilepsy	9	

Tonic convulsion	9
Ataxia	8
Encephalopathy	7
Tonic-clonic movements	7
Foaming at mouth	5
Polyneuropathy	4
Multiple sclerosis	4
Narcolepsy	4
Partial seizures	4
Bad sensation	3
Demyelination	3
Meningitis	3
Post ictal state	3
Seizure like phenomena	3
Tongue biting	3
Outcome	**1011**
Other	449
Not resolved	272
Unknown	**258**
Fatal	**16**
Resolved with sequelae	16
Other AESIs (# and % of total ASEs)	**8152**
Gender	7829
Female	5969
Male	1860
Unknown	N/A

Age	7479	
Infant	6	
2-11	9	
12-17	9	
18-64	6330	
>= 65	1125	
Diagnoses	8207	**Fever = 94% of category.**
Pyrexia	7666	**Herpes 391 cases.**
Herpes zoster (shingles)	259	
Inflammation	132	
Oral herpes	80	
Multiple organ dysfunction syndrome.	18	
Herpes virus infection	17	
Herpes simplex	13	
Ophthalmic herpes	10	
Herpes ophthalmic	6	
Herpes zoster reactivation	6	
Outcome	8218	
Other	5008	
Unknown	**1685**	**21%**
Not resolved	1429	
Fatal	**96**	**1%**

	AEs
Renal AESIs (# and % of total ASEs)	69
Gender	69
Female	46
Male	23
Unknown	N/A

Age		
Infant	1	
2-11	0	
12-17	0	
18-64	7	
>= 65	60	
Diagnoses		
Acute kidney injury	40	
Renal failure	30	
Outcome	**70**	
Fatal	**23**	**33%**
Unknown	**22**	**32%**
Not resolved	15	
Other	10	

	AEs	N= 42086
Respiratory AESIs 130		
Gender	130	
Female	72	
Male	58	
Unknown	N/A	
Age	**126**	
Infant	0	
2-11	0	
12-17	1	
18-64	47	
>= 65	78	
Diagnoses	**137**	
Respiratory failure	44	
Hypoxia	42	
Respiratory disorder	36	
ARDS	10	
Chronic respiratory syndrome	3	
Severe acute respiratory syndrome	2	
Outcome	137	
Other	47	
Fatal	**41**	**32%**
Unknown	**31**	**24%**
Not recovered	18	

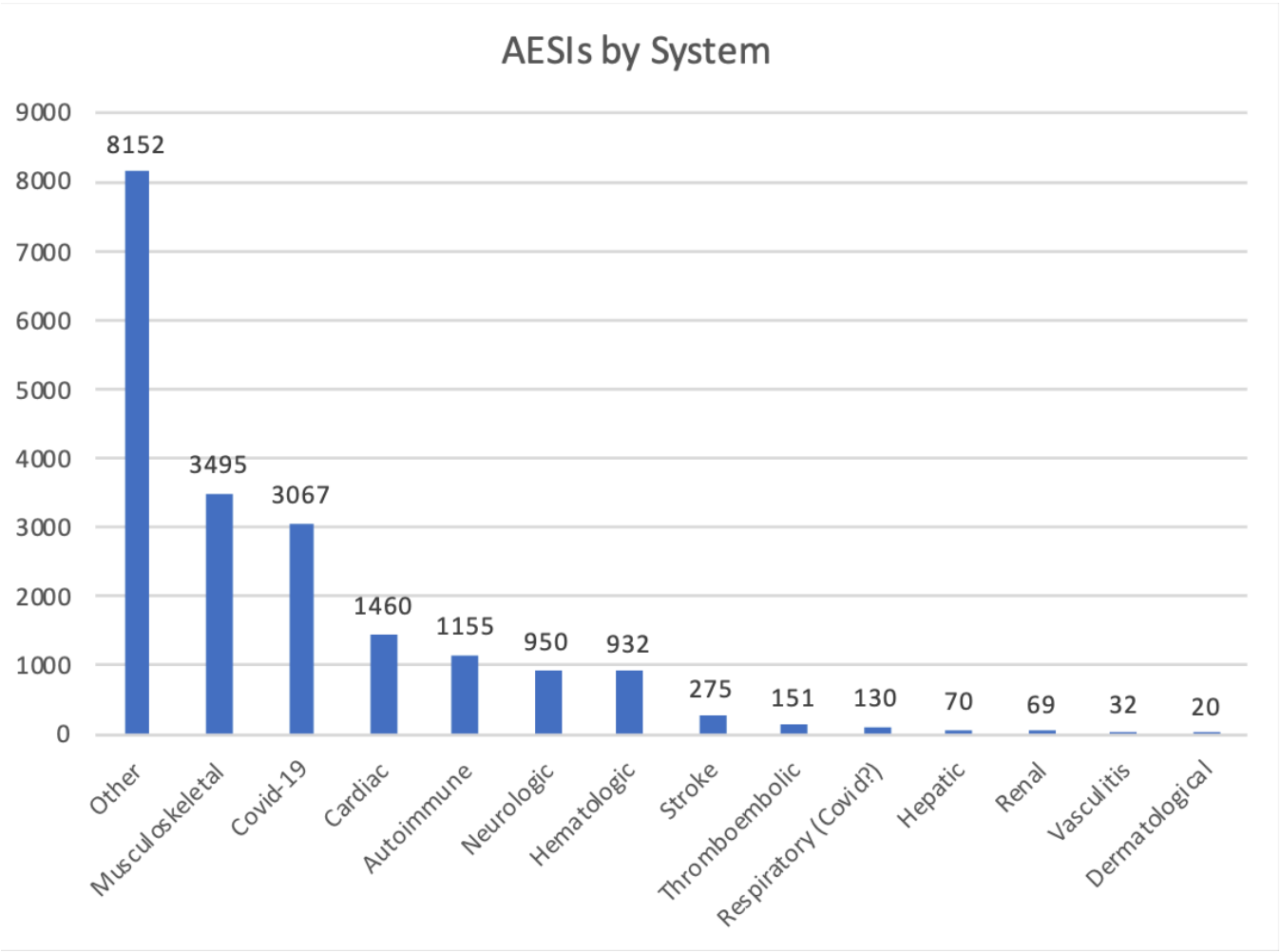
	AEs	N = 42086	
Stroke AESIs (# and % of total ASEs)	**275**		
Gender	**273**		
Female	182		
Male	91		
Unknown	N/A		
Age	**265**		
Infant	0		
2-11	1		
12-17	0		
18-64	59		
>= 65	205		
Diagnoses	**292**		
Ischemic	**237**		**81%**
Cerebrovascular accident	160		
Ischemic stroke	41		
Cerebral infarction	15		
Cerebral ischemia	3		
Cerebral thrombosis	3		
Cerebral venous sinus thrombosis	3		
Ischemic cerebral infarction	3		
Lacunar infarction	3		
Basal ganglia stroke	2		
Cerebellar infarction	2		
Thrombotic stroke	2		
Hemorrhagic	**55**		**19%**
Cerebral hemorrhage	26		
Hemorrhagic stroke	11		
Hemorrhage intercranial	5		
Subarachnoid hemorrhage	5		

Cerebral hematoma	4	
Basal ganglia hemorrhage	2	
Cerebellar infarction	2	
Outcome	**300**	
Not resolved	85	
Unknown	**83**	**28%**
Fatal	**61**	**20%**
Other	61	
Resolved with sequelae	10	

	AEs	N = 42086
Thromboembolic event (# and % of total ASEs)	**151**	
Gender	**144**	
Female	89	
Male	55	
Unknown	N/A	
Age	**136**	
Infant	0	
2-11	0	
12-17	0	
18-64	66	
>= 65	70	
Diagnoses	**151**	
Pulmonary embolism	60	
Thrombosis	39	
DVT	35	
Thrombophlebitis peripheral	6	
Venous thrombosis	4	
Embolism	3	
Microembolism	3	
Thrombophlebitis	3	
Venous thrombosis	3	
Blue toe syndrome	2	
Outcome	**169**	
Other	54	

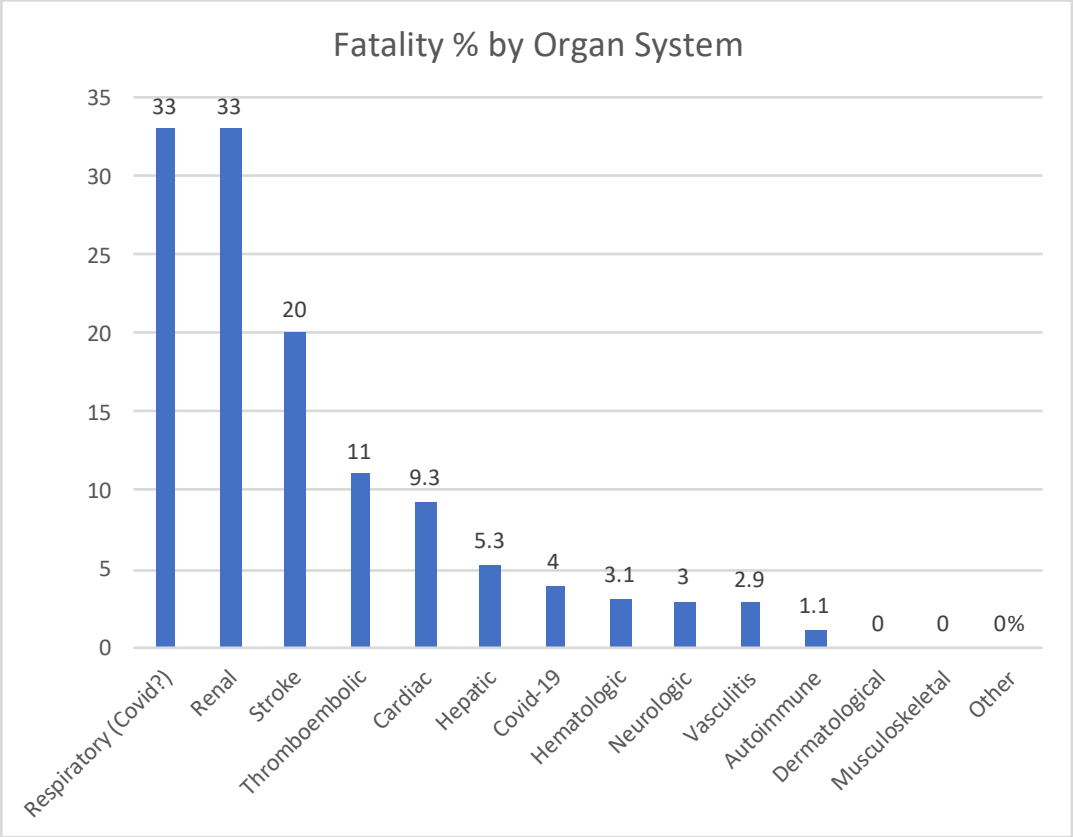
Not resolved	49	
Unknown	**42**	**25%**
Fatal	**18**	**11%**
Resolved with sequelae	6	

	AEs	N = 42086
Vasculitis (# and % of total ASEs)	**32**	
Gender	32	
Female	26	
Male	6	
Unknown	N/A	
Age	31	
Infant	0	
2-11	0	
12-17	0	
18-64	15	
>= 65	16	
Diagnoses	**32**	
Vasculitis	14	
Cutaneous vasculitis	4	
Vasculitic rash	4	
Giant cell arteritis	3	
Peripheral ischemia	3	
Bechet’s syndrome	2	
Hypersensitivity vasculitis	2	
Palpable purpura	1	
Takayasu's arteritis	1	
Outcome	**34**	
Other	13	
Not resolved	12	
Unknown	**8**	**24%**
Fatal	**1**	**3%**



Category*	N=
Musculoskeletal	3495
Covid-19	3067
Cardiac	1460
Autoimmune	1155
Neurologic	950
Hematologic	932
Stroke	275
Thromboembolic	151
Respiratory (Covid?)	130
Hepatic	70
Renal	69
Vasculitis	32
Dermatological	20

19958

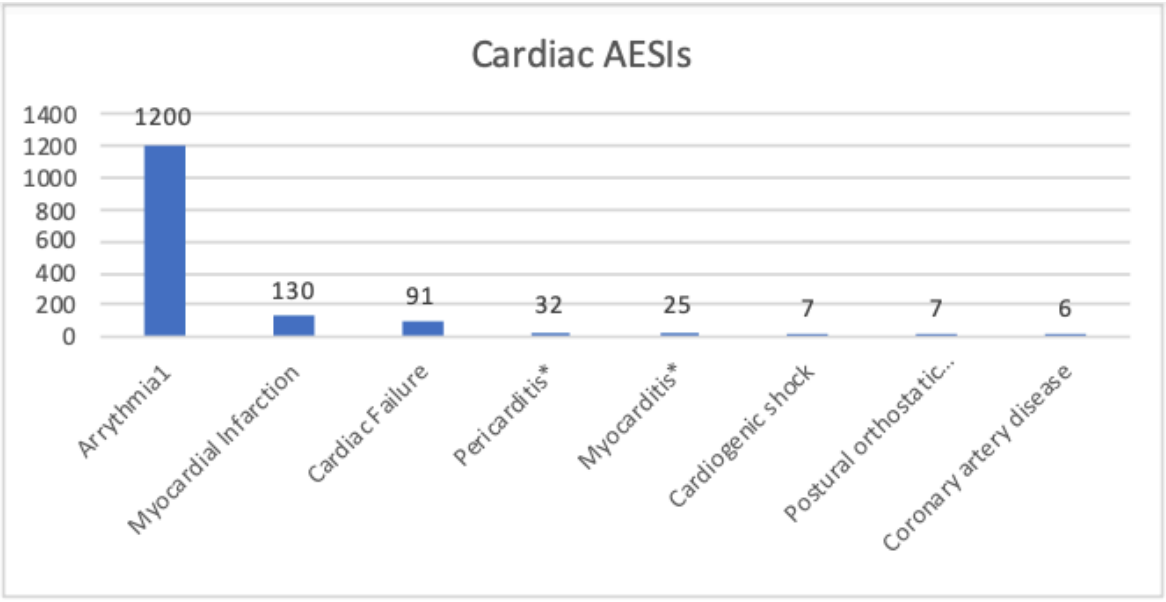


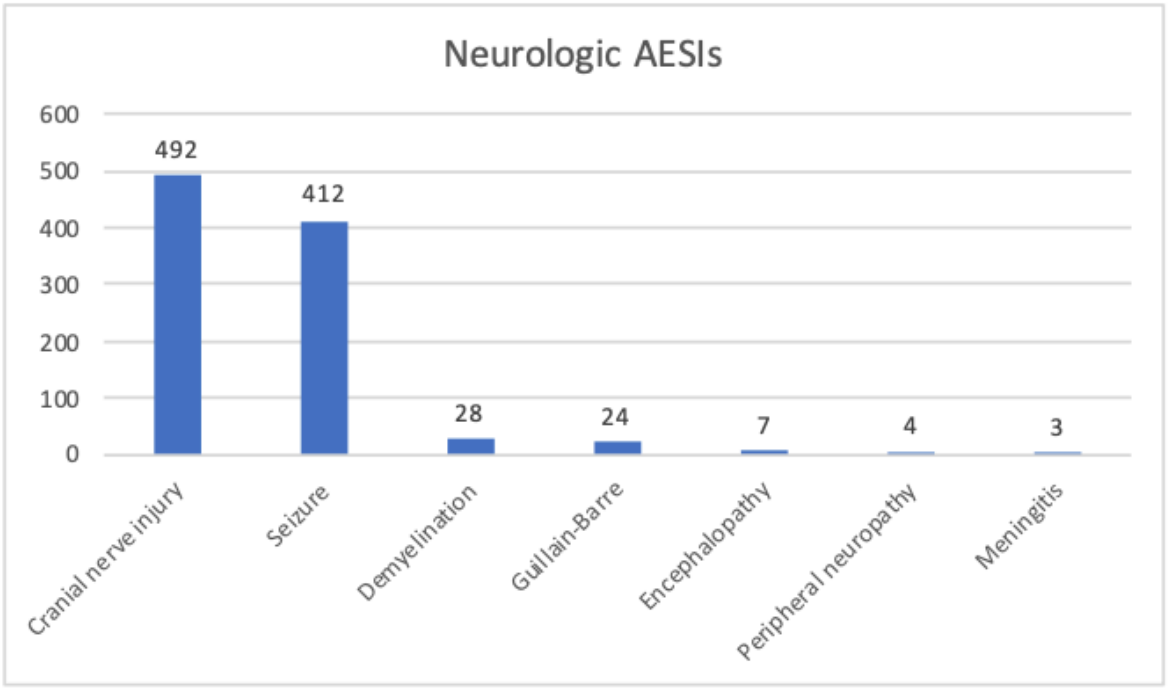
Category	% Fatality	% Unknown	# Unknown	Outcome
Respiratory (Covid?)	33	31%	22	70
Renal	33	31%	22	70
Stroke	20	28%	83	300
Thromboembolic	11	25%	42	169
Cardiac	9.3	26%	380	1444
Hepatic	5.3	52%	47	90
Covid-19	4	63%	2110	3360
Hematologic	3.1	34%	371	1082
Neurologic	3	30%	161	544
Vasculitis	2.9	24%	8	34
Autoimmune	1.1	29%	312	1078
Dermatological	0	29%	6	21
Musculoskeletal	0	30%	853	2809
Other	0%	26%	1685	6533
	Totals		**6102**	**17604**

AESI Outcome	**% Unknown outcome**	**31%**	
AESI Fatalities Category*	**N =**	Fatalities	Percent Fatal
Cardiac	1460	136	9%
Covid-19	3067	136	4%
Other	8152	96	1%
Stroke	275	61	22%
Respiratory (Covid?)	130	41	32%
Hematologic	932	34	4%
Renal	69	23	33%
Thromboembolic	151	18	12%
Neurologic	950	16	2%
Autoimmune	1155	12	1%
Hepatic	70	5	7%
Vasculitis	32	1	3%
Dermatological	20	0	0%
Musculoskeletal	3495	0	0%
Totals	**19958**	**579**	**3%**

Table 1 Fatalities	1223
Fatalities accounted for	579
Missing	644
Missing %	53%

AEs + AESIs	**Cases not reported or lost**	
Table 1	"Relevant cases" per Pfizer	42086
Table 7	Organ systems	19958
Table 1	Outcome Unknown	9400
	Known Outcome	29358
	"Missing"	**12728**
		30%

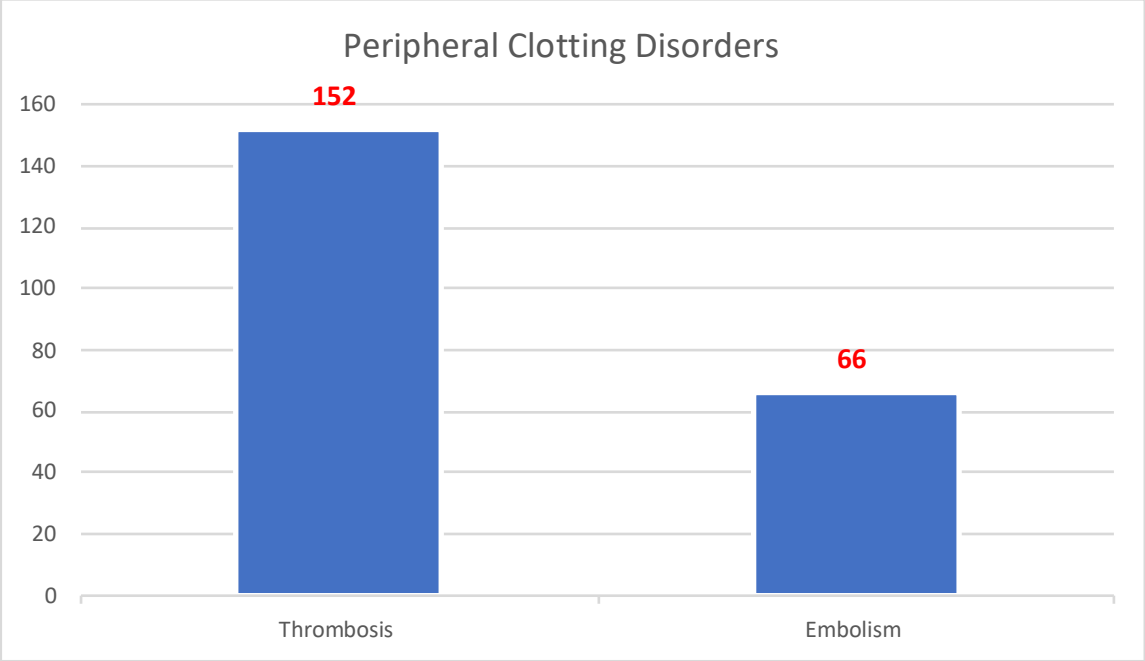


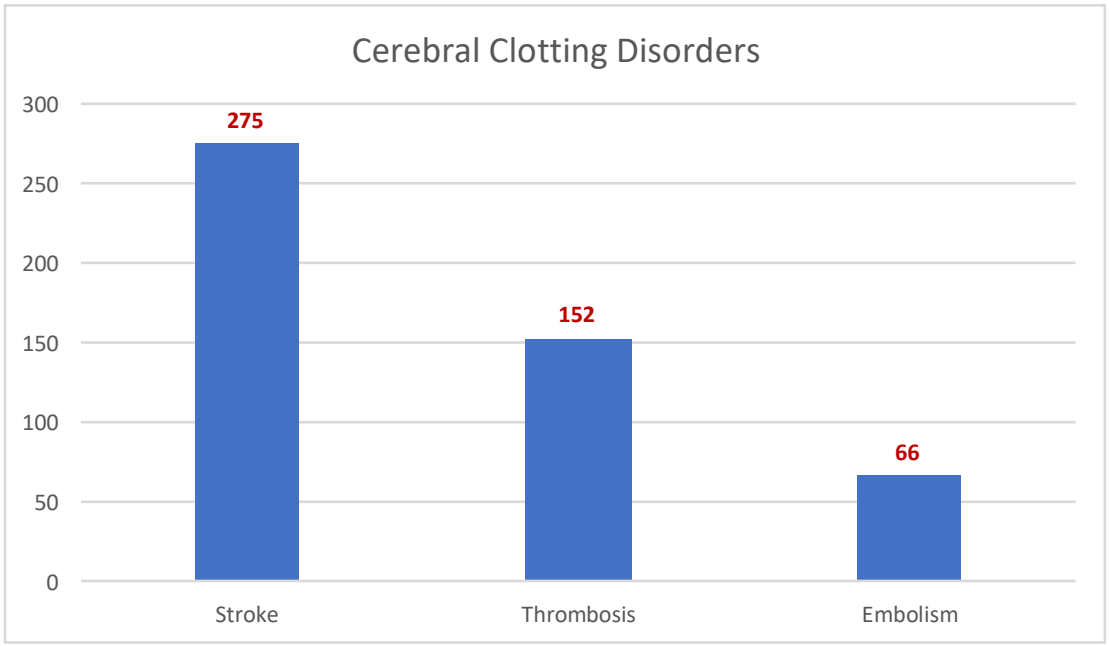


Neurologic

Cranial nerve injury	492
Seizure	412

Demyelination	28
Guillain-Barre	24
Encephalopathy	7
Peripheral neuropathy	4
Meningitis	3
	970





Stroke	275
Thrombosis	152
Embolism	66

As the numbers of those receiving the vaccine rose, **Pfizer was confronted with such a flood of Adverse Event reporting that they had to hire 2,400 employees to handle the volume.** *5.3.6 postmarketing experience.pdf* reports on 42,086 subjects or patients considered relevant with 93,473 Adverse Events (AEs) or Adverse Events of Special Interest (AESIs), although there appears to have been 137,205 actual events. [https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf] As noted, at least four or more appendixes may have been omitted, as the document references "Appendix 5," which is not included in the document.

The Pfizer report, *Reissue 5.3.6*, presents a selection of that reporting. Denominators are largely not provided, making statistical analyses of prevalence nearly impossible. This document is highly significant in identifying AEs/AESIs signal detection that would lead responsible scientific and medical professionals to:

- **Incorporate warnings of specific disorders resulting from Pfizer's COVID-19 BNT162b2 vaccine** in Public Service Announcements (PSAs) and in written, signed, and witnessed Informed Consents.
- Acknowledge that **these disorders were identifiably associated with BNT162b2** as of December 2020 through data capture completion February 28, 2021:

    - **Covid-19 was one of the most common AEs/AESIs.** According to document *5.3.6*, COVID-19 was the third most common adverse event. The top two most common adverse events were Arthralgia (achiness, etc. around or near joints) and Pyrexia (raised body temperature, fever). The COVID-19 cases were unbundled and scattered through the reporting.
    - **Clotting disorders:** stroke, thrombosis, embolism
    - **Bleeding disorders:** hematoma, hemorrhage
    - **Neurological disorders:** seizures and nerve damage to both central and peripheral nervous systems
    - **Autoimmune disorders:** arthritis, cerebritis, peri cardiomyopathies
    - **Organ system damage:** cardiac, hematopoiesis, reproductive
    - **Viral Antibody-Dependent Enhancement (VADE)**
- **Intensify targeted data collection and detailed investigation** of these disorders including a statically, sufficiently powered series of autopsies and outcome studies.
- Establish an agency up to **manage in a medically responsible way all reported AEs/AESIs patients.**

Additionally, the primary source document is modified to include pericarditis and myocarditis in the cardiac organ system rather than under autoimmune disorders. This is done because the AESIs are organized as organ systems. The conclusion that these inflammatory disorders of the heart are a result of an immune system disorder is in itself a remarkable admission. This topic is worthy of follow-up investigations.

Similar adjustments to some diagnostic categories are also present. For, example, arthritis and rheumatoid arthritis were moved from the Musculoskeletal to the Autoimmune category. This is significant because the sudden appearance of these disorders put them in the Autoimmune category – until otherwise proven.

Another interesting inclusion is the case of "Tachycardia" (1,098 cases). **Tachycardia** means elevated heart rate. Heart rates go up roughly 10 beats per minute for each degree of temperature gain. Strangely, there were 7,666 cases of Pyrexia (fever) using Celsius degrees that eliminated all temperature elevations between 99.6- and 100.3-degrees Fahrenheit. The **under-reporting of fevers makes this reporting questionable**. Were these "Tachycardias" cases actually cases of erratic heartbeat (arrhythmia) that affect the heart's upper chambers? The matter can only be resolved with **raw data access that has not been provided.**

Finally, in Table 2, 1,972 **cases of Lymphadenopathy (swelling of the lymph nodes) appear without any reporting of low white blood cell count (lymphocytopenia)** or measuring of infection or dysfunction including the formation of cancers. Similar concerns can be directed toward the **absence in the reporting of Troponin and d-dimer levels.** Without the raw data, we have no

way of knowing just how high d-dimer levels were. D-dimers are protein fragments present in the blood after a blood clot. This is significant because of the correlation between high d-dimer levels and frequency of blood clots.

These are just a few of the concerns raised by Pfizer's *5.3.6 postmarketing experience* document. [https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf] Once raw data has been released in usable form, many outstanding questions can be answered.

By April 30, 2021, Pfizer and the FDA knew diverse, dangerous, sometimes life-altering, and even fatal adverse events resulted from the administration of the mRNA vaccines. Yet, the FDA and Pfizer failed to inform the public of these side effects except for a June 25, 2021, warning about myocarditis and pericarditis. To date, that is the only mRNA vaccines' adverse event warning published. [https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021] Informed consent is not possible without clear, public warnings about clotting, bleeding, neurological, and autoimmune disorders, as well as organ systems' damages and Viral Antibody-Dependent Enhancement. [https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html]

Report 32: "Pfizer Used Dangerous Assumptions, Rather than Research, to Guess at Outcome" by Robert Chandler, MD, MBA – Team 5.

At the launch of widespread mass inoculation of the public with Pfizer's mRNA vaccine, BNT162b2, media, physicians' spokespeople, and government officials communicated widely that the injected drug would be retained at the injection site muscle tissue and in local lymph nodes. The components were supposed to be metabolized in a day or so, leaving only induced SARS CoV-2 Spike antigen to evoke a therapeutic immune response. A short pulse of drug effect would be followed, they claimed, by limited production of Spike antigen.

However, newly released internal Pfizer documents show that this is not true. In fact, the injection causes widespread distribution of the material in tissues and this distribution persists for at least two days, and probably much longer. These facts are the exact opposite of what was publicized.

A cluster of FDA-released Pfizer documents — "*Final Report: A Tissue Distribution Study of a [3H]-Labeled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats*"[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf], *2.4 NONCLINICAL OVERVIEW* [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf], "*MODULE 2.6.5. PHARMACOKINETICS TABULATED SUMMARY"* [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_26_pharmkin-tabulated-summary.pdf] and the heavily redacted report "*R&D STUDY REPORT No. R-20-0072 – EXPRESSION OF LUCIFERASE-ENCODING MODERNA AFTER I.M. APPLICATION OF GMPREADY ACUITAS LIPID NANOPARTICLE FORMULATION* "[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_R-20-0072.pdf] — all examine tissue distribution of Pfizer's mRNA vaccine BNT162b2. These documents will be addressed in this report.

Pfizer Study 185350," *Final Report: A Tissue Distribution Study of a [3H]-Labeled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rat"*, is one of 21 preclinical Prizer studies involving mice, rats and rhesus macaque non-human primates. Study No. 185350 (Sponsor Reference ALC-NC-0552) was summarized in Pfizer's "2.4 Nonclinical Overview" and was separately published as a Final Report dated September 24, 2020.

Contained in that document is the following identification of the source:

Test Facility Study No. 185350 REDACTED
SPONSOR: Acuitas,
6190 Agronomy Road,
Ste. 402,

Vancouver, V6T 1Z3 Canada
Sponsor Reference No. ALC-NC-0552

This study was made up of 42 male and 21 female Wistar Han rats. These rats were injected with 50 or 100 micrograms of BNT162b2 mRNA/LNP (lipid nanoparticle) product labeled with a radioactive tracer material, 3H. Then the rats were sacrificed at intervals of 0.25 hours (15 minutes); 1 hour; 2 hours; 4 hours; 8 hours; and then at 1 and 2 days.

The results of 21 male and 21 female sacrificed rats are presented.

The 100-microgram dose was associated with loss of weight and apparent toxicity in two animals. Unfortunately, the full results of the 100-microgram dose were not presented at all. [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p. 11.]

Initially, 21 male rats were dosed at 100 µg mRNA/animal. Some adverse clinical signs were observed after approximately 24 hours post-dose and a subsequent review of the data showed concentrations were well detected in tissues. After discussions with the Sponsor, the target dose level was lowered to 50 µg mRNA/animal by amendment for the remainder of the study. Reference is made to the 100 µg mRNA /animal group in some sections of the report, however, the results are not discussed.

This is very important. **The 100-microgram dose was considered too toxic to continue to use in the experiment, so the dosage was cut in half. 100 micrograms are the amount in the Moderna injections.**

The 50-microgram dose was not safe. One female rat in the 50-microgram dose exhibited piloerection and hunched posture. [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p.19.]

The injection did not stay at the injection site, as we were promised it would. Rather, following injection, the drug was persistent at the injection site, with a third of the dose remaining in muscle tissue for two days in males, and a sixth of the dose remained in females for the same duration.

Timepoint (h)	Injection site (µg equiv lipid/g)		Injection site (% dose)	
	Male	Female	Male	Female
0.25	219.940	36.566	32.887	6.815
1	587.670	199.950	68.829	36.411
2	529.210	93.144	39.053	24.094
4	619.850	56.227	47.710	9.056
8	299.590	125.930	18.731	24.993
24	267.170	122.540	31.957	26.295
48	268.770	61.088	32.823	16.426

But it did not all stay in the deltoid muscle. From the injection site in the deltoid muscle, mRNA/Lipid Nanoparticles appeared in blood and plasma fifteen minutes after injection and persisted for the entire duration of the two-day study.

Timepoint (h)	Blood (µg equiv lipid/g)		Plasma (µg equiv lipid/mL)		Blood:plasma ratio	
	Male	Female	Male	Female	Male	Female
0.25	3.003	0.936	6.035	1.894	0.48	1.15
1	2.809	5.928	5.379	10.884	0.49	0.54
2	4.028	6.773	8.714	9.091	0.46	0.64
4	3.400	2.698	8.755	4.251	0.42	0.60
8	2.000	0.628	3.573	1.147	0.56	0.55
24	1.274	0.544	2.621	0.945	0.49	0.57
48	0.535	0.305	1.085	0.524	0.50	0.58

On page 20 of "*Final Report: A Tissue Distribution Study of a [3H]-Labeled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rat*," the authors note that widespread distribution to "most tissues" occurs by the time of first analysis at 15 minutes after injection.

There was greater accumulation in blood when compared to plasma, and males generally had higher concentrations than females with lower blood to plasma ratios. No explanation for these differences was offered.

The major tissues that contained the drug concentration, aside from muscle at the injection site, were identified as being the liver, spleen, adrenal glands, and ovaries. The drug persisted in tissues throughout the duration of the study. The meaning and potential implications of the persistence in tissues was not addressed. [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p. 21.]

Timepoint (h)	Values expressed as µg equiv lipid/g)						
	Liver		Spleen		Adrenal glands		Ovaries
	Male	Female	Male	Female	Male	Female	Female
0.25	1.151	0.323	0.354	°0.313	0.302	°0.240	°0.104
1	4.006	5.244	2.140	2.801	0.580	2.388	1.339
2	9.574	12.370	5.255	10.213	1.206	4.232	1.638
4	18.525	14.569	8.945	11.646	2.569	3.206	2.341
8	27.916	25.172	24.434	19.747	6.387	7.218	3.088
24	23.360	15.119	22.819	17.341	19.948	7.595	5.240
48	18.164	30.411	19.550	27.155	21.476	14.942	12.261

°Mean includes results calculated from data less than 30 cpm above background

Timepoint (h)	Liver		Spleen		Adrenal glands		Ovaries
	Male	Female	Male	Female	Male	Female	Female
0.25	0.995	0.209	0.014	°0.011	0.001	°0.001	°0.001
1	2.834	2.907	0.087	0.098	0.002	0.012	0.009
2	7.629	7.030	0.232	0.418	0.005	0.015	0.008
4	15.027	8.699	0.351	0.419	0.012	0.018	0.016
8	21.519	14.580	1.118	0.845	0.026	0.043	0.025
24	19.901	10.977	0.957	0.685	0.083	0.049	0.037
48	13.953	18.357	0.914	1.146	0.104	0.108	0.095

°Mean includes results calculated from data less than 30 cpm above background

Top: highest mean concentrations. Bottom: equivalent % dose.

The next two tables present the overall tissue distribution data from this study. It is reasonable to conclude, thus, that BNT162b2 is distributed throughout the body and persists for at least two days, the duration of the study. [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, pp. 7-8.] Tissue specimens were harvested but, unfortunately, no microscopic analysis of these specimens is presented at all, so potential damage to various organs was not evaluated.

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [^{3}H]-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 ad libitum
Method of Administration:	Intramuscular injection
Dose:	50 µg [^{3}H]-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 min	1 h	2 h	4 h	8 h	24 h	48 h	0.25 min	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

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [^{3}H]-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 min	1 h	2 h	4 h	8 h	24 h	48 h	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h
Lymph node (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	0.092	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
Testes (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[a]	0.815	0.515	0.550	0.510	0.555	0.530	0.540	--	--	--	--	--	--	--

A separate pharmacokinetic study, "PF-07302048," looked at the persistence of the LNP (lipid nanoparticle) transport vessel with a test mRNA inside consisting of LNP coating wrapped around Luciferase mRNA, Figure 2.4.3-1 below. ["*R&D STUDY REPORT No. R-20-0072 – EXPRESSION OF LUCIFERASE-ENCODING MODRNA AFTER I.M. APPLICATION OF GMPREADY ACUITAS LIPID NANOPARTICLE FORMULATION"*, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_R-20-0072.pdf.]

The object of this study was to follow the LNP vessel in plasma and liver, and then measure transcription of mRNA inside target organs to validate the delivery model using the bioluminescent properties of Luciferase to identify transcription of the mRNA in target tissues. [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_R-20-0072.pdf]

From this study, we learn that the two measured components of the lipid nanoparticle coating, ALC-0315 [(4-hydroxybutyl) azanediyl]di(hexane-6, 1-diyl) bis (2-hexyldecanooate)] and ALC-0159 (2-[2-(polyethylene glycol)-2000]-N, N-ditetradecylacetamide) are detectable in plasma after 300 hours – that is to say, 12.5 days – which fact raises the issue of how long the contents of the LNP vessel with the mRNA inside persists, and what the implications are of prolonged occupation of host cells by this material. In this study, the BNT162b2 was injected intravenously, accelerating the dissemination of the drug. [*2.4 NONCLINICAL OVERVIEW*, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p.16.]

Figure 2.4.3-1. Plasma and Liver Concentrations of ALC-0315 and ALC-0159 in Wistar Han Rats After IV Administration of LNPs Containing Surrogate Luciferase RNA at 1 mg/kg

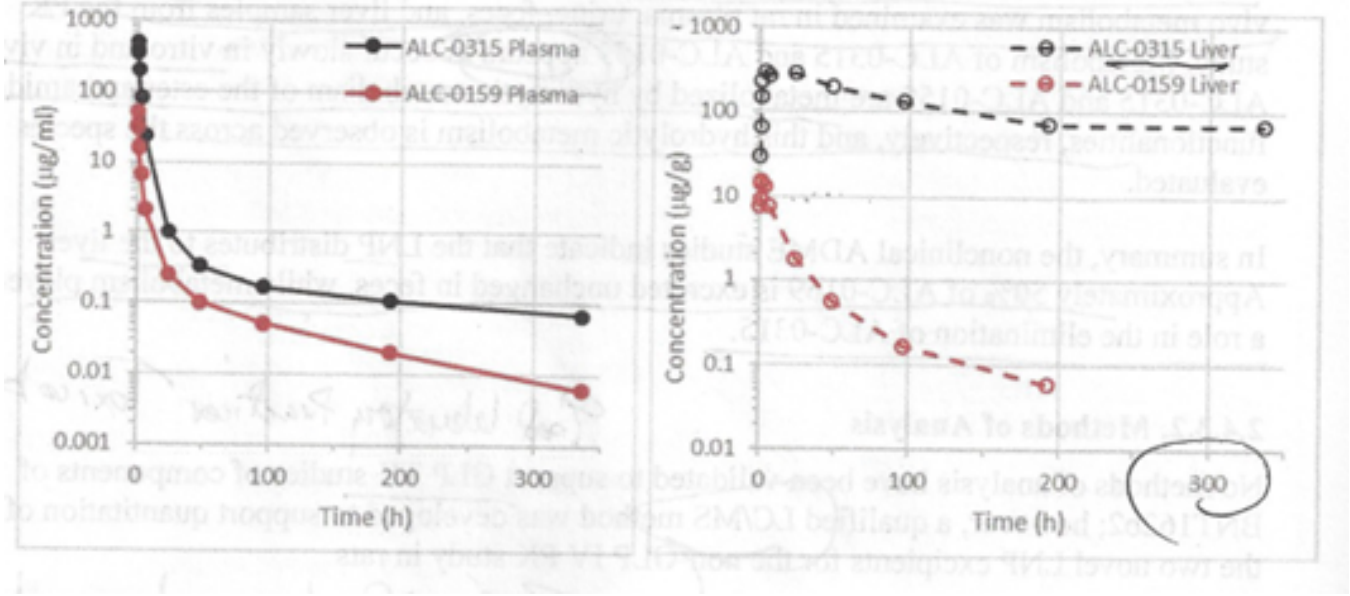


Figure 1: From R&D STUDY REPORT No. R-20-0072 – EXPRESSION OF LUCIFERASE-ENCODING MODRNA AFTER I.M. APPLICATION OF GMPREADY ACUITAS LIPID NANOPARTICLE FORMULATION.

This study of the biodistribution of the LNP coating containing Luciferase mRNA found that not only was the mRNA transcribed, but the LNP "vessel" components ALC-0315 and ALC-0159 were retained in the liver and in the plasma for at least 12.5 days. The fate of the Luciferase mRNA was not discussed.

With respect to degradation of the mRNA component, we learn from "*2.4 Nonclinical Overview"* that Pfizer/Acuitas did not study at all the degradation of the synthetic mRNA in BNT162b2. Similarly, there was no analysis by Pfizer of protein products from BNT162b2 provided. [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p.20.]

The protein encoded by the RNA in BNT162b2 is expected to be proteolytically degraded like other endogenous proteins. RNA is degraded by cellular RNases and subjected to nucleic acid metabolism. Nucleotide metabolism occurs continuously within the cell, with the nucleoside being degraded to waste products and excreted or recycled for nucleotide synthesis. Therefore, no RNA or protein metabolism or excretion studies will be conducted.

Several serious questions are raised by these results:

1. How long does the BNT162b2 mRNA persist in human tissues? Where does it go in the host cell? How long does it persist inside the cell? What proteins does it produce, and for how long?
2. Is there any possibility that the BNT162b2 mRNA can be transcribed into DNA, then incorporated into the host genome? If this happens what are the implications?
3. What are the toxicities from the lipid nanoparticle coating?
4. Was Pfizer obligated to answer these questions prior to human testing?
5. Doesn't proper informed consent require answers to these questions?

Fortunately, answers to these important questions are beginning to appear:

1a. Duration of mRNA in tissues:
In a July 19, 2022, article, the essayist Joomi reviews the topic of how long BNT162 b2 containing mRNA stabilized by a synthetic nucleotide 1N-methyl pseudouridine persists in human tissues. [https://joomi.substack.com/p/were-still-being-misled-about-how]

A January 2022 human lymph node biopsy study from Stanford University found that the mRNA from both Pfizer and Moderna persists for at least two months, which was the duration of the study. [https://www.cell.com/action/showPdf?pii=S0092-8674%2822%2900076-9]

1b. Proteins produced from BNT162b2 mRNA:
Spike protein is produced after the mRNA is transcribed and has been found in vivo for at least four months after inoculation. [https://joomi.substack.com/p/were-still-being-misled-about-how]

Proteins transcribed from the mRNA have not been completely characterized yet SARS-CoV-2-like Spike protein has been identified as long as four months after inoculation with LNP/mRNA in human exosomes. Toxicity of Spike protein has been described and is reviewed in the essay "We're still being misled about how long the mRNA vaccines last in the body." [https://joomi.substack.com/p/were-still-being-misled-about-how]

2. What is the fate of BNT162b2 mRNA?
We were informed that "RNA is required for protein synthesis, does not integrate into the genome, is transiently expressed, and is metabolized and is eliminated by the body's natural mechanisms and, therefore, is considered safe." [*Alberer, M. et al. Safety and immunogenicity of a mRNA rabies vaccine in healthy adults: an open-label, non-randomized, prospective, first-in-human phase 1 clinical trial. Lancet 90, 1511-1520 (2017).*] [*Sahin, U. e al. Personalized RNA mutanome vaccines mobilize poly-specific therapeutic immunity against cancer. Nature 547, 222-226 (2017).*]

However, Alden, et al., reporting in *Current Issues in Molecular Biology* 2022, 44, 1115-1126, found BNT162b2 mRNA is reverse transcribed into host DNA beginning six hours after contact with BNT162b2:

"In the BNT162b2 toxicity report, no genotoxicity nor carcinogenicity studies have been provided. Our study shows that BNT162b2 can be reverse transcribed to DNA in liver cell line Huh7, and this may give rise to the concern if BNT162b2-derived DNA may be integrated into the host genome and affect the integrity of genomic DNA, which may potentially mediate genotoxic side effects. At this stage, we do not know if DNA reverse transcribed from BNT162b2 is integrated into the cell genome. Further studies are needed to demonstrate the effect of BNT162b2 on genomic integrity, including whole genome sequencing of cells exposed to BNT162b2, as well as tissues from human subjects who received BNT162b2 vaccination." [https://www.mdpi.com/1467-3045/44/3/73/htm]

This study did not identify DNA transcribed from BNT162b2 mRNA in the host genome following transcription.

However, Zhang et al., working at Massachusetts Institute of Technology, demonstrated fragments of SARS-CoV-2 mRNA integrated in host DNA in "Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues," published in 2021 in *PNAS,* vol. 118, no. 21:

"We show here that SARS-CoV-2 RNA can be reverse-transcribed and integrated into the genome of the infected cell and be expressed as chimeric transcripts fusing viral with cellular sequences. Importantly, such chimeric transcripts are detected in patient-derived tissues." [https://www.pnas.org/doi/10.1073/pnas.2105968118]

So, scientists are getting close to knowing whether BNT162b2, with its synthetic mRNA, is translated into host DNA and is now a permanent part of human genetic material. If so, the next step is to determine what the implications are.

3. What are the toxicities from the lipid nanoparticle coating?
More research is required to understand the implications of LNP concentration in various organ tissues. It is thought that the PEG component (the polyethylene glycol that coats the LNP) is responsible for anaphylaxis, an often rapid-onset major physiologic event that requires emergency treatment.

4. Was Pfizer obligated to answer these questions prior to human testing?
5. Doesn't proper informed consent require answers to these questions?
The answers to questions 4 and 5 are "yes," and the reasons should be obvious now. Basic information about functioning of this mRNA product, BNT162b2, was not known at the time of

mass inoculation; and, therefore, a proper risk, benefits and complications discussion was compromised by lack of information. Informed consent is not possible in such a situation.

In conclusion, many negatively consequential shortcuts were made in the development of BNT162b2.

Many omissions in basic research evaluation of BNT162b2 were kept hidden, and there was outright misinformation regarding some of the work that was done.

Assumptions rather than actual research to determine where BNT162b2 goes, what it does, and how long it lasts were made that proved to be false and constitute intentional mis/dis/mal information. We were told that the prodrug, BNT162b2, consisting of a lipid nanoparticle coating of synthetic messenger ribonucleic acid (modRNA), would be deposited in muscle tissue at the injection site and would be migrate to local lymphatics prior to rapid degradation producing Spike antigens for a limited period of time that would produce a desired immune response.

However, Pfizer in its very early Phase 1 trial with mice, rats, and rhesus non-human primates learned that the LNP/mRNA is rapidly disseminated throughout the body and remained in tissues for as long as it was studied, 48 hours for BNT162b2 and 12.5 days for the LNP/Luciferase mRNA test product.
No effort was expended to determine what proteins are produced by the modRNA, what their physiological actions are and how long they are produced as well as what toxicities and adverse events might be anticipated with widespread usage of the LNP/mRNA prodrug.

FOIA requests for internal documents from federal health care agencies, independent review board members, approximately 140 clinical investigators and Pfizer personnel should be made.
Billions of doses were administered to billions of people. The scale of this potentially massive medical misstep is large.

Ten months to develop novel gene therapy for a novel virus is well short of the five to 10 years usually required to develop, test and refine such a product. After billions of doses have been given to children and adults around the world, possibly altering the course of human evolution, the public is now seeing the unfortunate consequences of cutting corners.

Report 33: "Pfizer, FDA, CDC Hid Proven Harms to Male Sperm Quality, Testes Function, from mRNA Vaccine Ingredients" by Amy Kelly.

When the COVID-19 vaccine rollout to the public began in late 2020, medical professionals, public health agencies, and government spokespeople all assured the American public that the novel mRNA vaccines did not cause negative systematic effects to human bodies. They promised the public, many of whom were skeptical about the safety of a drug brought to market at "warp speed," that the vaccines were "safe and effective." ["Operation Warp Speed: Accelerated Covid-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges." Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address M*anufacturing Challenges | U.S. GAO*, U.S. Government Accountability Office, 11 Feb. 2021, https://www.gao.gov/products/gao-21-319.] ["Safety of Covid-19 Vaccines." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 8 Aug. 2022, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.]

As we know, those who questioned or challenged the "safe and effective" assurances were dismissed as "anti-vaxxers" and accused of wanting to kill others, especially the elderly. [Gostin, Lawrence O., and Eric A. Friedman. "This Is the Best Evidence Yet That Anti-Vaxxers Kill." *Yahoo! News*, Yahoo!, 23 June 2022, https://news.yahoo.com/best-evidence-yet-anti-vaxxers-225950487.html.]

Due to this pressure, during the push to vaccinate everyone against COVID-19, few medical and public health experts spoke out about the need for long-term studies to protect Americans against possible catastrophic vaccine-related outcomes, including against possible negative impacts on fertility.

This attack on challengers to public health's all out push, and the resulting censorship of the emerging problem, resulted in catastrophic harms to male fertility.

Pfizer's own documents and other medical studies show:

1. mRNA vaccine ingredients can be transferred from one person to another via skin-to-skin contact, inhalation and via "sexual intercourse," through bodily fluids. That is to say, vaccine "shedding" can occur via sexual contact, including via exposure to semen. ["A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals," Protocol Amendment 14, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, pp. 213, 246, 398, 431, 575, 607, 751, 783, 918, 948, 1073, 1103, 1226, 1255, 1378, 1406, 1522, 1549, 1663, 1688, 1813, 1836, 1949, 1969, 2081, 2100, 2211, 2228, and 2337.] In other words, according to Pfizer's own internal documents, a vaccinated man can expose his sexual partner to the vaccine ingredients, via ejaculation.

2. Pfizer did not test "male reproductive toxicity". Male reproductive toxicity is defined as adverse effects (negative impacts) related to sexual function and fertility in adult male ["Summary of the Public Assessment Report for COVID-19 Vaccine Pfizer/BioNTech." *GOV.UK*, GOV.UK, https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine.]

3. Pfizer also did not test for adverse effects from vaccinated men's semen, on the development of their offspring. ["Reproductive Toxicity March 2017 – SCHC." *org*, SCHC-OSHA Alliance GHS/HazCom Information Sheet Workgroup, Mar. 2017, https://www.schc.org/assets/docs/ghs_info_sheets/schc_osha_reproductive_toxicity_4-4-16.pdf.]

4. mRNA vaccine ingredients travel throughout the body and gather in organs, including in the testes. ["A Tissue Distribution Study of a [3H]-Labeled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats," https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p. 24.]

5. mRNA vaccines resulting in "anti-sperm antibodies" – that is to say, antibodies that treat sperm as an "invader", and damage or kill it – is a known adverse event related to this form of vaccination. ["5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021," https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf, p. 30.] [Salvador, Zaira, and Sandra Fernández. "What Are Antisperm Antibodies? – Causes & Treatment." *InviTRA*, 8 Jan. 2019, https://www.invitra.com/en/antisperm-antibodies/.]

6. mRNA vaccines cause a staggering drop in semen concentration and total motile count. [Gat, Itai, et al. "Covid-19 Vaccination BNT162B2 Temporarily Impairs Semen Concentration and Total Motile Count among Semen Donors." *Wiley Online Library*, Andrology, 17 June 2022, https://onlinelibrary.wiley.com/doi/10.1111/andr.13209.]

7. By suppressing discussion of this information, public health agencies, medical professionals, and governments globally denied and continue to deny men true informed consent.

Transfer of mRNA Vaccine Ingredients Between Humans

We stated above that Pfizer knew that men could transmit the vaccine ingredients to their partners via sexual intercourse. Pfizer's clinical trial protocol shows the company suspected that negative fertility impacts may occur in men, from its vaccine. Male trial participants had to follow specific "Male Participant Reproductive Inclusion Criteria." These were spelled out in all fourteen versions of Pfizer's protocol:

"Male participants are eligible to participate if they agree to the following requirements during the intervention period and for at least 28 days after the last dose of study intervention, which corresponds to the time needed to eliminate reproductive safety risk of the study intervention(s)"

The inclusion criteria requirements stated that men must:

- Refrain from donating sperm.

In addition, the men in the Pfizer trials must either:

- Abstain from heterosexual intercourse with a female of childbearing potential as their preferred and usual lifestyle. They must be abstinent from heterosexual intercourse with a female of childbearing age on a long-term and persistent basis and they must agree to remain abstinent.

OR the men in the Pfizer trial:

- Must agree to use a male condom when engaging in any activity that allows for passage of ejaculate to another person.

- In addition to male condom use, a highly effective method of contraception may be considered in WOCBP (women of childbearing age) partners of male participants." ["A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals," Protocol Amendment 14, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, pp. 213, 246, 398, 431, 575, 607, 751, 783, 918, 948, 1073, 1103, 1226, 1255, 1378, 1406, 1522, 1549, 1663, 1688, 1813, 1836, 1949, 1969, 2081, 2100, 2211, 2228, and 2337.]

In other words, the men in the Pfizer trial agreed to abstain from heterosexual intercourse with childbearing age women or else, if they did have intercourse with women who could bear children, they agreed to use a condom and were advised to add an effective additional method of contraception. Reassuring, right? The Pfizer study constructs regarding total abstinence from sex with women who could bear children, or else the use of both condoms and other

contraception, suggest that Pfizer suspected that vaccinated men's ejaculate could affect both women and unborn children conceived during the trial or after.

Pfizer's protocol documents also explain:

"An EDP (Exposure During Pregnancy) occurs if:

- …A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.

- A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:
    - …A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception." [Protocol Amendment 14, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, pp. 111, 319, 501, 677, 848, 1009, 1162, 1314, 1461, 1603, 1747, 1889, 2023, 2153, 2279, and 2346]

Clearly, Pfizer showed strong concern about and precautions against exposure to the "study intervention" – that is, the mRNA vaccine – via bodily fluids contact such as exposure to ejaculate, and via skin-to-skin contact.

Yet as recently as July 2022, the Centers for Disease Control and Prevention (CDC) assured Americans that COVID-19 mRNA vaccine shedding – "the release or discharge of any of the vaccine components in or outside of the body" – is a "myth." ["Myths and Facts about Covid-19 Vaccines." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 20 July 2022, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html.] Indeed a recent FOIA via America First Legal reveals that Carol Crawford of the CDC coordinated with Twitter employees to target tweets (including one by Dr. Naomi Wolf) about "shedding," as an example, as CDC put it, of "misinformation." But it was not, per Pfizer's own documents, disinformation at all. According to the manufacturer, "shedding" was a real concern.

mRNA Vaccine's Adverse Effects on Male Reproduction

National Institutes of Health (NIH) boldly stated on February 1, 2022, "COVID-19 vaccination does not reduce chances of conception…" ["Covid-19 Vaccination Does Not Reduce Chances of Conception, Study Suggests." *National Institutes of Health*, U.S. Department of Health and Human Services, 1 Feb. 2022, https://www.nih.gov/news-events/news-releases/covid-19-vaccination-does-not-reduce-chances-conception-study-suggests.] However, the NIH's statement was and is false.

Pfizer did not initially evaluate its vaccine's male "reproductive toxicity" – i.e., adverse effects on fertility in adult males – during clinical trials because the company was in a rush: "The absence of reproductive toxicity data is a reflection of the speed of development to first identify and select COVID-19 mRNA Vaccine BNT162b2 for clinical testing and its rapid development to meet the ongoing urgent health need." ["Summary of the Public Assessment Report for COVID-19 Vaccine Pfizer/BioNTech." *GOV.UK*, GOV.UK, https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine.]

But when Pfizer eventually did look at the mRNA vaccine's impact on male fertility, the company used "untreated male" rats for its "Reproductive and Developmental Toxicity" studies. The untreated males mated with female rats that had been dosed with BNT162b2, Pfizer's mRNA vaccine. [*2.4 Nonclinical Overview*, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p. 29.]

In other words, Pfizer tested fertility effects on female mammals dosed with its mRNA product but left the males undosed.

Throughout the Pfizer documents, the issue arises that studies were constructed so that Pfizer (and the FDA) did not find what it chose not to look for.

How do scientists determine a new drug's adverse effects on male fertility if they give only one-half of the reproducing population – the females – the treatment in question?

That same Pfizer document goes on to say, "Macroscopic and microscopic evaluation of male and female reproductive tissues from the repeat-dose toxicity studies with BNT162b2 showed no evidence of toxicity." [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p. 30.]

This statement seems to indicate that the study sought to evaluate whether the vaccine was passed through bodily fluids and/or skin contact during intercourse between the treated females and untreated males.

But how convenient – the male rats' reproductive tissues were declared free of toxicity; but the male rats had never been vaccinated at all.

2.4.4.6. Reproductive and Developmental Toxicity

Reproductive and developmental toxicity assessments were made with BNT162b2 (V9) (Study 20256434). BNT162b2 was administered by IM injection at the human clinical dose (30 µg RNA/dosing day) to 44 female Wistar Han rats (F0) 21 and 14 days prior to mating with untreated males and on GD 9 and 20, for a total of 4 dosing days. A separate control group of 44 F0 females received saline by the same route and regimen.

Following completion of a mating phase with untreated males, 22 rats/group underwent caesarean-section on GD 21 and were submitted to routine embryo-fetal development evaluations. The remaining 22 rats/group were allowed to litter and development of the offspring was observed until PND 21.

There were no BNT162b2-related deaths during the study. IM administration of BNT162b2 before and during gestation to female Wistar rats resulted in nonadverse clinical signs and macroscopic findings localized to the injection site as well as transient, nonadverse body weight and food consumption effects after each dose administration. These maternal findings are all consistent with administration of a vaccine and an inflammatory/immune response.

There were no BNT162b2-related effects on any mating or fertility parameters. There were no BNT162b2-related effects on any ovarian, uterine, or litter parameters, including embryo-fetal survival, growth, or external, visceral, or skeletal malformations, anomalies, or variations. There were no effects of BNT162b2 administration on postnatal offspring (F1) development, including postnatal growth, physical development (pinna unfolding and eye

opening), reflex ontogeny (pre-weaning auditory and visual function tests), macroscopic observations, and survival.

Figure 1: Untreated Male Rates in Pfizer's 2.4. Nonclinical Overview.

Since there were no vaccinated male rats at all in the Pfizer reproductive studies during its internal trials, it appears Pfizer, and since the human males in the Pfizer study had to promise to abstain from intercourse with childbearing age women or else use a condom PLUS another effective contraceptive – it appears that Western public health agencies decided to test the effects of mRNA vaccines on men's reproduction simply by using the "intervention" – the mRNA vaccine – on human subjects, male as well as female, during a mass vaccination campaign.

mRNA Vaccine Ingredients Travel Throughout the Body and Gather in Organs

As we have seen in other DailyClout/War Room Pfizer Documents Research Volunteer Reports, medical and public health agency professionals assured the U.S. public that the COVID vaccine ingredients remained in the deltoid muscle when injected and did not disperse throughout the body. [Chandler, Robert W. "Pfizer Used Dangerous Assumptions, Rather than Research, to Guess at Outcomes." *DailyClout*, DailyClout, 9 Aug. 2022, https://dailyclout.io/pfizer-used-dangerous-assumptions-rather-than-research-to-guess-at-outcomes/.]

However, the FDA received the Pfizer document," A Tissue Distribution Study of a [3H]-Labeled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats," on November 9, 2020, over a month before Pfizer's vaccine received Emergency Use Authorization (EUA) and began to be injected into humans worldwide. The document shows shocking biodistribution results. ["A Tissue Distribution Study of a [3H]-Labeled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats," https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p. 24.]

"Biodistribution" is a method of tracking where given ingredients travel in the body of an experimental animal or a human subject. The document clearly demonstrates that Pfizer's mRNA vaccine contents – including lipid nanoparticles – enter the bloodstream, travel throughout the body, and accumulate in organs, including in the testes. Reference Table 1, "Mean (Sexes-Combined) Concentration of Total Radioactivity in Whole Blood, Plasma and (Continued) Tissues Following Single Intramuscular Administration of [3H]-08-A01-C01 to Wistar Han Rats – Target Dose Level: 50 µg mRNA/Animal; 1.29 mg Total Lipid/Animal – Results expressed as total lipid concentration (µg lipid equiv/g (mL)) and % of administered dose," shown below. ["A Tissue Distribution Study of a [3H]-Labeled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats," https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p. 24.]

Table 1 (Continued) **Mean (Sexes-Combined) Concentration of Total Radioactivity in Whole Blood, Plasma and Tissues Following Single Intramuscular Administration of [^{3}H]-08-A01-C01 to Wistar Han Rats**

Target Dose Level: 50 µg mRNA/Animal; 1.29 mg Total Lipid/Animal

Results expressed as total lipid concentration (µg lipid equiv/g (mL)) and % of administered dose

Sample	Total Lipid Concentration (µg lipid equiv/g (or mL))							% of Administered Dose						
	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h
Small intestine	0.030	0.221	0.476	0.879	1.279	1.302	1.472	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	2.471	7.734	10.296	22.091	20.080	23.353	0.013	0.093	0.325	0.385	0.982	0.821	1.030
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
Testes (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	1.000	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	1.970	4.369	5.401	3.049	1.314	0.909	0.420	-	-	-	-	-	-	-
Plasma	3.965	8.132	8.903	6.503	2.360	1.783	0.805	-	-	-	-	-	-	-
Blood:plasma ratio	0.815	0.515	0.550	0.510	0.555	0.530	0.540	-	-	-	-	-	-	-

- =Partial tissue taken therefore not applicable/not applicable

How did medical and public health leaders remain so staunchly firm in their position that mRNA vaccination did *not* impact male fertility, even as they had access to Pfizer's biodistribution study?

These experts who were swearing that the mRNA vaccine ingredients did not leave the injection site also had access to a 2018 NIH-published paper that clearly shows that nanoparticles — of which lipid nanoparticles are subtype [Murthy, Shashi K. "Nanoparticles in Modern Medicine: State of the Art and Future Challenges." *International Journal of Nanomedicine*, Dove Medical Press, June 2007, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2673971/.] — could pass into the testes from the blood and cause male reproductive harm. The 2018 study showed that NPs accumulate in the testes to damage sperm quality and amount, as well as their "motility", or ability to move effectively, a requirement of conception:

"NPs [nanoparticles] can pass through the blood-testis barrier…then accumulate in reproductive organs. NP accumulation damages organs (testis, epididymis…) by destroying Sertoli cells, Leydig cells, and germ cells, *causing reproductive organ dysfunction that adversely affects sperm quality, quantity, morphology, and motility*…"? [Wang, Ruolan, et al. "Potential Adverse Effects of Nanoparticles on the Reproductive System." *International Journal of Nanomedicine*, U.S. National Library of Medicine, 11 Dec. 2018, https://pubmed.ncbi.nlm.nih.gov/30587973/.]

To appreciate fully how NPs harm key components of healthy male sexual development and function, one must understand the roles of the damaged organs and cells, all crucial to male sexual health and even to male sexual development, mentioned above.

- The "epididymis" is involved in transporting sperm from the testes. [Boskey , Elizabeth. "Anatomy and Function of the Epididymis." *Verywell Health*, Verywell Health, 30 June 2022, https://www.verywellhealth.com/epididymis-anatomy-4774615.]

- "Sertoli cells" are vital to the development of the testes. "Sertoli cells are of critical importance for testis development…[and] are the master regulators of testis development…" [Pelosi, Emanuele, and Peter Koopman. "Development of the Testis." *Sertoli Cell – an Overview | ScienceDirect Topics*, Science Direct, 2017, https://www.sciencedirect.com/topics/engineering/sertoli-cell.] "During [the sperm developmental process], developing sperm cells are closely linked with the Sertoli cells." [Carlson, Bruce. "Gametogenesis." *Sertoli Cell – an Overview | ScienceDirect Topics*, Science Direct, 2014, https://www.sciencedirect.com/topics/engineering/sertoli-cell.]

- "Leydig cells" are present in the testicular interstitial tissue. Their main function is to produce *testosterone for the maintenance of sperm creation and development and male body development.* [Huhtaniemi, Ilpo, and Katja Teerds. "Leydig Cell." *Leydig Cell – an Overview | ScienceDirect Topics*, Science Direct, 2018, https://www.sciencedirect.com/topics/neuroscience/leydig-cell.] Thus, when Leydig cells are damaged, one could say that physical masculinity itself is damaged. This is especially urgent to consider when we reflect on the fact that small boys and teenagers, who have not reached or completed puberty, are being injected with mRNA vaccines containing lipid nanoparticles.

- "Germ cells" "are…precursors of…sperm cells. ["Germ Cells – Definition, Embryonic to Gametes, vs Somatic Cells." *MicroscopeMaster*, MicroscopeMaster.com, https://www.microscopemaster.com/germ-cells.html.]

Thus, these excerpts and citations show that:

1. lipid nanoparticles gather in human organs including the testes,
2. nanoparticles are detrimental to normal male reproduction, and
3. Big Pharma and public health agencies knowingly gambled with harms to boys' and male teens' sexual development, and with all ages of males' testosterone levels, older males' sperm counts, and male fertility.

A Sperm-Related mRNA Vaccine Adverse Event That Causes Male Infertility

An alarming mRNA vaccine-induced reproductive Adverse Event of Special Interest (AESI) came to light at the end of February 2021. Pfizer's own document lists "anti-sperm antibody positive" among its 1,290 AESIs. ["5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021," https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf, p. 30.]

What is an "ASA"?

According to *inviTRA*, a certified medical magazine created by doctors and fertility experts, "The presence of antisperm antibodies (ASA) in the ejaculate is an immune cause of male infertility. The adhesion of antibodies to sperm affects their motility, making the sperm's journey to the egg highly difficult or even impossible." [Salvador, Zaira, and Sandra Fernández. "What Are Antisperm Antibodies? – Causes & Treatment." *InviTRA*, 8 Jan. 2019, https://www.invitra.com/en/antisperm-antibodies/.]

This late February 2021 Pfizer document confirming anti-sperm antibodies is the first documented indication I found within the Pfizer records that Pfizer's mRNA COVID-19 vaccine negatively impacts male fertility.

Note that Pfizer knew about this male infertility AESI almost *12 months* prior to the clearly false NIH statement from February of 2022: "COVID-19 vaccination does not reduce chances of conception…" ["Covid-19 Vaccination Does Not Reduce Chances of Conception, Study Suggests," 1 Feb. 2022.] The Food and Drug Administration (FDA) knew about this AESI by April 30, 2021. ["5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021," https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf]

For nearly a year, then, the FDA, public health agencies, and medical organizations ignored this "cause of male infertility" contained in the Pfizer documents – all of which were sent to the FDA. Then they lied about it.

They kept silent for a year and then misled the public, rather than alerting the public. The mass vaccination campaign continued, without even a brief pause, and again, men were denied informed consent.

The Suspension of Informed Consent for Men Continues

Contrary to established medical ethics, Pfizer and public health agencies did not disclose the true impacts of mRNA gene therapy vaccines on male fertility and, thus, as noted above, denied men informed consent. ["Informed Consent – Definition, Examples, Cases, Processes." *Legal Dictionary*, Legal Dictionary, 7 Dec. 2015, https://legaldictionary.net/informed-consent/.]

In fact, the medical establishment, governments, public health agencies worldwide, Big Pharma, and Big Tech colluded to suppress COVID vaccine facts, risks, and alternatives. [Tucker, Jeffrey A, and Debbie Lerman. "Besties: Twitter, Facebook, Google, CDC, NIH, WHO." *Brownstone Institute*, Brownstone Institute, 3 Aug. 2022, https://brownstone.org/articles/besties-twitter-facebook-google-cdc-nih-who/.]

In January of 2021, the American Society for Reproductive Medicine posted the "Joint Statement Regarding COVID-19 Vaccine in Men Desiring Fertility from the Society for Male Reproduction and Urology (SMRU) and the Society for the Study of Male Reproduction (SSMR)" encouraging COVID vaccination for men, including for male fertility treatment patients, despite their having no data about its impact on male reproductive health:

"As of January 9, 2021, there are no data about the impact of the COVID-19 vaccine on male…fertility. […] the American Society for Reproductive Medicine does not recommend withholding the vaccine from patients who are planning to conceive, and emphasizes that patients undergoing fertility treatment and pregnant patients should be encouraged to receive vaccination based on eligibility criteria." ["Update No. 11 Covid-19 Vaccination December 16, 2020 – ASRM." *American Society for Reproductive Medicine*, American Society for Reproductive Medicine, 9 Jan. 2021, https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/covid-19/covidtaskforceupdate11.pdf.]

Additionally, for men, SMRU and SSMR recommended:

- The COVID-19 vaccine should not be withheld from men desiring fertility who meet criteria for vaccination.

- COVID-19 vaccines should be offered to men desiring fertility, similar to men not desiring fertility, when they meet criteria for vaccination.

The organization went on to blame declines in sperm production on COVID-19 vaccine-related fevers. ["Joint Statement Regarding Covid-19 Vaccine in Men Desiring Fertility from the Society for Male Reproduction and Urology (SMRU) and the Society for the Study of Male Reproduction (SSMR)." *ASRM*, American Society for Reproductive Medicine, 9 Jan. 2021, https://www.asrm.org/news-and-publications/covid-19/statements/joint-statement-regarding-covid-19-vaccine-in-men-desiring-fertility-from-the-society-for-male-reproduction-and-urology-smru-and-the-society-for-the-study-of-male-reproduction-ssmr/.]

The ASRM, SMRU, and SSMR – all reproductive societies – stated in unison in 2021 that there were no data about fertility impacts *and* that men "desiring fertility" should take the drug for which fertility impacts are unknown.

But how could they advise that men take the vaccine if there were no data proving that it would not affect fertility?

The slanted messaging continued when the "Semen Analysis Parameters Following Pfizer's COVID-19 Vaccine" clinical study said, "Unfounded claims in the popular media linked a possible correlation between the COVID-19 vaccine and potential…male infertility. Currently, there is no information in the medical literature which examines semen analysis parameters following the COVD-19 vaccine." ["Semen Analysis Parameters Following Pfizer's COVID-19 Vaccine." Full Text View – *ClinicalTrials.gov*, ClinicalTrials.gov, 2 Mar. 2021, https://clinicaltrials.gov/ct2/show/NCT04778033.]

Again, how exactly could public speculation about potential mRNA vaccine-induced infertility be "unfounded" when those leading the study admit that, as of February 2021, there were no data to show that such a concern was invalid?

The push to brush off fertility concerns continued throughout 2021.

In September 2021, *Fertility and Sterility* journal published a study which concluded, "After receiving the two doses of the vaccines, we did not observe a clinically significant sperm parameter decline within the cohort, suggesting the vaccines do not negatively impact male fertility potential."

However, the study was flawed. It went on to admit: "The limitations of the study include the small number of men enrolled; limited generalizability beyond young, healthy men; short follow-up; and lack of a control group." [Gonzalez, Daniel C., et al. "Sperm Parameters before and after COVID-19 mRNA Vaccination." *JAMA*, JAMA Network, 20 July 2021, https://jamanetwork.com/journals/jama/fullarticle/2781360.] [Gonzalez, Daniel, et al. "Effect of COVID-19 Mrna Vaccines on Sperm Quality." *Fertility and Sterility*, Published by Elsevier Inc., 17 Sep. 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8446925/.]

True experiments always include at least one control group that does not receive the experimental treatment. Without a control group, a study's outcome cannot be certain. Yet, despite long-established scientific norms being cast aside, "the science" told men in this case that COVID vaccines would not negatively affect their fertility.

At the end of 2021, a Chinese study published truths that previous Western studies had refused to acknowledge. The study validated fertility-related vaccine concerns: "Although several fertility societies have announced that COVID-19 mRNA vaccines are unlikely to affect fertility, there is no denying that the current evidence is very limited, which is one of the reasons for vaccine hesitancy…" The Chinese study went on to say, "…given the potential damage of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to the reproductive system, some individuals suspect that the vaccine which mimics the virus (mRNA vaccine) may also affect fertility via the same mechanism." It even addressed the fact that COVID vaccines were rushed to market:

"Admittedly, data on COVID-19 mRNA vaccines are incomplete when compared with traditional vaccines based on long-term studies with large samples." [Chen, Fei, et al. "Effects of COVID-19 and Mrna Vaccines on Human Fertility." *Human Reproduction (Oxford, England)*, Oxford University Press, 27 Dec. 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8689912/.]

Finally, cracks were appearing in mRNA vaccine and fertility information dam, and those cracks prefaced a stunning revelation that was about to drop.

Pfizer's mRNA COVID-19 Vaccine in Fact Cause an Astonishing Drop in Male Fertility

On June 22, 2022, *Andrology* published a bombshell study, "Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors." The study, which did not even include the effects of additional booster injections, showed a staggering drop in male fertility, with an average decrease of 22.1% across the study group, from the initial injections alone. The study concluded, "Systemic immune response after BNT162b2 vaccine is a reasonable cause for transient semen concentration and TMC (total motile count) decline." [Gat, Itai, et al. "Covid-19 Vaccination BNT162B2 Temporarily Impairs Semen Concentration and Total Motile Count among Semen Donors." *Wiley Online Library*, Andrology, 17 June 2022, https://onlinelibrary.wiley.com/doi/10.1111/andr.13209.]

Each study participant provided multiple semen samples throughout the study's duration as follows:

- T0 = pre-vaccination baseline
- T1 = 15-45 days post-vaccination
- T2 = 75-120 days post-vaccination
- T3 = 150+ days post-vaccination

The investigators studied participants for five months (T1-T3 above) after they received Pfizer's vaccine. Table 2 below demonstrates the troubling results, which have a 95% confidence interval. T3 collection averaged a time frame of 174 (+/- 26.8) days.

So, at close to six months post-vaccination, sperm concentration, motility, and total motile count were all still in significant states of decline versus pre-vaccination levels. Sperm concentration had not recovered at all and was, in fact, at its lowest point yet.

TABLE 2 Percentage and absolute change[1] compared to T0 as reference measured by repeated measures analysis (total samples)

		Change[1]	95% CI		p-Value
Semen volume	T0[2]	Ref			
	T1	10%	−3.9%	25.8%	0.214
	T2	−4.5%	−14.7%	7%	
	T3	9%	−6.3%	26.8%	
Sperm concentration	T0	Ref			
	T1	−14.5%	−27.9%	1.4%	**0.044**
	T2	**−15.4%**	**−25.5%**	**−3.9%**	
→	T3	−15.9%	−30.3%	1.7%	
Sperm motility	T0	Ref			
	T1	2.7	−1	6.6	0.058
	T2	−1.9	−4.9	1.7	
→	T3	−4.1	−8.2	0.1	
Total motile count	T0	Ref			
	T1	−2%	−19.9%	20.1%	**0.027**
	T2	**−22.1%**	**−35%**	**−6.6%**	
→	T3	−19.4%	−35.4%	0.6%	

[1]Volume, concentration and TMC are presented as *percentage* change compared to T0 while motility change is presented as *absolute* change.
[2]T0 – pre-vaccination baseline control; T1, T2 and T3 – short, intermediate and long-term evaluations after 15–45, 75–125 and over 145 days after vaccination date, respectively.

Figure 3: From "Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors," p. 4.

Despite these alarming outcomes, the published study went on to encourage vaccination: "Since misinformation about health-related subjects represents a public health threat our findings should

support vaccinations programs. Further studies concentrating on different vaccines and populations (ex. subfertile patients) are urgently required." [Gat, Itai, et al., 17 June 2022, https://onlinelibrary.wiley.com/doi/10.1111/andr.13209, p. 6.]

Alarmingly, men continue to receive incomprehensibly contradictory messages, being told to keep injecting the mRNA vaccines even when the study that contains these exhortations, clearly demonstrates adverse fertility results – to men.

The Public Is Left with More Questions Than Answers

This review of documents and studies, culminating with one that shows shocking data about mRNA vaccines conclusively reducing men's fertility, gives rise to important questions:

- When, if at all, do men's fertility fully recover from such a drastic decline after a two-dose vaccination course?

- Do boosters, which twenty-nine percent of the world's population have received as of July 31, 2021, have an even stronger negative impact on men's fertility? [Holder, Josh. "Tracking Coronavirus Vaccinations around the World." *The New York Times*, The New York Times, 29 Jan. 2021, https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html.]

- Does giving mRNA COVID-19 vaccines to pre-pubescent and adolescent males affect their normal sexual development and ability to reproduce, as the implication of the study on NPs in testes suggest it may?

- Is the decline in birth rates being seen in highly vaccinated countries [Chudov, Igor. "Igor's Newsletter." *Substack*, Igor Chudov, https://igorchudov.substack.com/.] at least in part due to how mRNA vaccines have conclusively affected male fertility?

- What factors in the well-documented "baby die-off" being seen around the globe may come from the effects of men being vaccinated with mRNA vaccines? [Wolf, Naomi. "Dear Friends, Sorry to Announce a Genocide." *Substack*, Outspoken with Dr Naomi Wolf, 30 May 2022, https://naomiwolf.substack.com/p/dear-friends-sorry-to-announce-a.]

- Why did pharmaceutical companies, public health officials, medical professionals, and governments tell the public that mRNA COVID-19 vaccines did not affect men's fertility when they had no data to support such a conclusion?

- Why, when health officials, doctors, and governments received data confirming mRNA vaccines negatively impact men's fertility, did they not raise the alarm and fight to give men informed consent?

The public must demand answers to these questions from pharmaceutical companies, world governments, public health agencies, and the medical establishment. Those entities blocked men from having the ability to give informed consent and made them unwitting participants in an ongoing clinical trial of a novel gene therapy.

Such assaults on humanity and its ability to reproduce, and especially, the potential harms to boys, youths, and unborn babies, must be challenged. Those responsible for human experimentation that demonstrably harmed male fertility, must be held accountable.

Amy Kelly *is the Program Director for the War Room/DailyClout Pfizer Documents Analysis Project.*

Report 34: "Women Have Two and a Half Times Higher Risk of Adverse Events Than Men. Risk to Female Reproductive Functions Is Higher Still." by Robert Chandler, MD, MBA – Team 5.

The Pfizer documents demonstrate a strong signal that women have far more adverse events than males, particularly when considering reproductive organs and function. Primary source material from Pfizer shows a strong, sex-linked Adverse Event (AE) difference. Two major data collections, Reissue of Pfizer's "5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-FEB-2021" and "APPENDIX 2.1 Cumulative Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class," show substantially greater numbers of Adverse Events in women contrasted with men. This signal is particularly strong for the reproductive organs and their functions. Women have approximately three times the risk of Adverse Events than do males, and the specific risk to the reproductive organs and their functions is even stronger.

Two large data sets in the Pfizer confidential document collection, released pursuant to a court order, report consistent sex differences in the absolute number and percentage of Adverse Events (AEs) and Adverse Events of Special Interest (AESI). This report will examine primary source documents that collect Adverse Events at two points in time – February 28, 2021, the end of first two and a half months following widespread inoculation with Pfizer's COVID-19 vaccine, and then at a second time ending on March 15, 2022.

Most AEs appear to have been spontaneously reported through a mechanism the public is still waiting to learn about, which means they were not part of a well-regulated and proactive surveillance program and may underestimate the actual frequency of such events.

Many people having a complication related to Pfizer's Lipid Nanoparticle Messenger Ribonucleic Acid (LNP/mRNA) prodrug, BNT162b2 (the Pfizer COVID-19 vaccine), are not aware of how to report or are unable to report in cases of a severe complication. Alternatively, reporting may be being actively suppressed.

As a review of the entries in Appendix 2.1, the 170-page registry of 4,563,770 Adverse Events logged in by April 15, 2022, shows that over-reporting and, in some cases, questionable relevance of the reporting in some disease categories is a possibility.

Sex Differences Example 1:
Reissue of Pfizer's 5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-FEB-2021

The FDA reissued Pfizer's 5.3.6 Adverse Events document on April 1, 2022, and it offers a summary of Adverse Events and Adverse Events of Special Interest after injection of BNT162b2, Pfizer's LNP/mRNA vaccine.

This data set comprises 42,086 subjects from the first two and a half months following the Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA) on December 11, 2020.

Table 1 below shows a tally of Adverse Events and Adverse Events of Special Interest by organ system from the 5.3.6 Reissue document, although it must be pointed out that some cases were reassigned to organ categories by the author.

For instance, myopericarditis was moved from Pfizer's Autoimmunity assignment to Cardiac based on the organ involved rather than the assumed disease process. **Table 1: AEs and ASEIs up to 2/28/2021**

In every category, females substantially outnumber males. Charts 1 and 2 are graphical representations of this data.

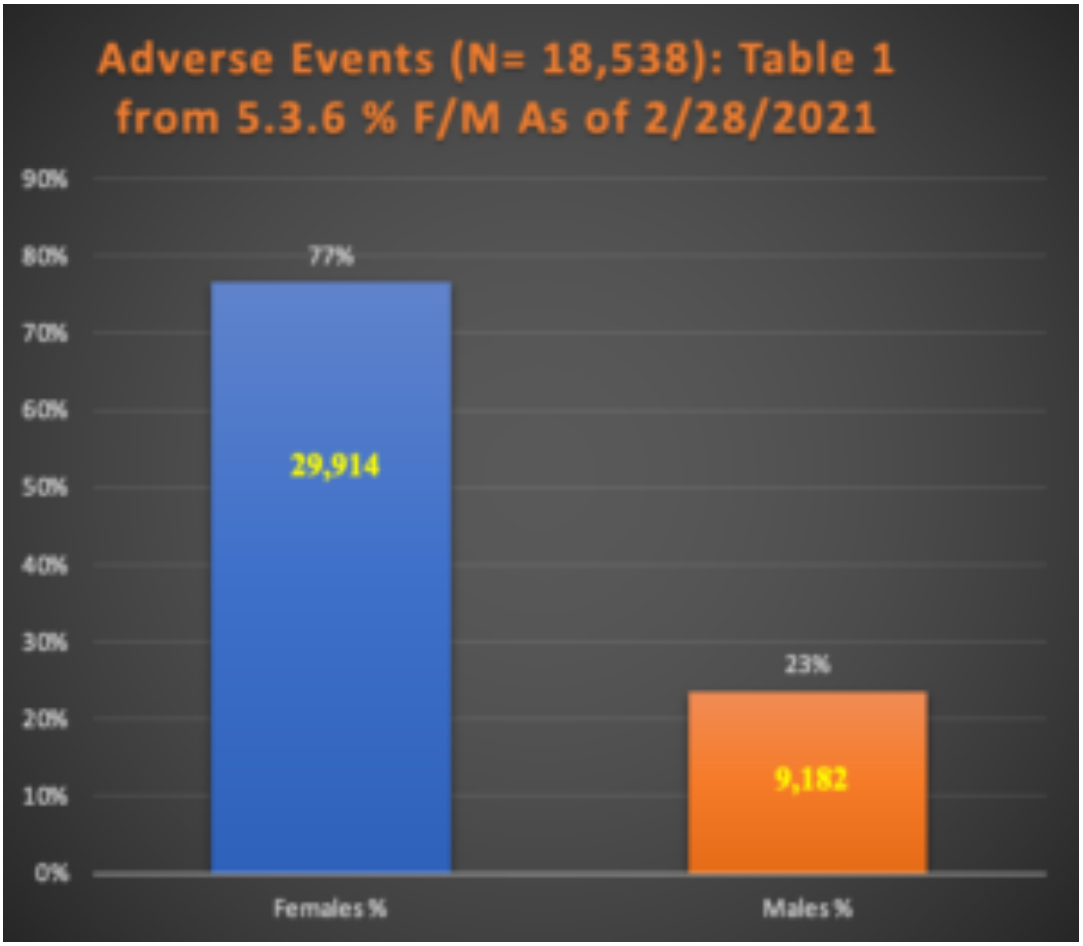
Study	**Females %**	**Males %**	**F**	**M**	**N =**	**Unk**	**p**
Table 1 from 5.3.6	77%	23%	29914	9182	42086	2990	$p < 0.001$
Table 7 from 5.3.6							
Autoimmune	81%	19%	682	156	838	N/A	$p < 0.001$
Cardiac	77%	21%	1076	291	1403	36	$p < 0.04$
Covid-19	66%	34%	1650	844	3067	573	$p < 0.001$

Dermatologic	94%	6%	17	1	19	1	**See note below** **Chart 1**
Hematologic	75%	25%	676	222	898	0	**p = 0.385**
Hepatic	61%	37%	43	26	70	0	p =0.019
Musculoskeletal	80%	20%	2760	711	3471	0	p < 0.001
Neurologic	69%	31%	623	283	927	21	p < 0.001
Other (Pyrexia and Herpes)	76%	24%	5969	1860	7829	0	**p = 0.527**
Renal	67%	33%	46	23	69	0	**p = 0.085**
Respiratory	55%	45%	72	58	130	0	p < 0.001
Stroke	67%	33%	182	91	273	0	p = 0.001
Thromboembolic event	62%	38%	89	55	144	0	p < 0.001
Vasculitis	81%	19%	26	6	32	0	**p = 0.549**
Total excl. Unknown	75%	25%	13911	4627	18538		

Chart 1 illustrates this finding with 29,914 females with AEs compared with only 9,182 for males. (i.e., $p < 0.001$).

It should be noted that "p," as shown in $p < 0.001$ above, indicates the level of significance. Commonly, $p < 0.05$ is the minimal level of acceptance, meaning there is a 95% chance that the number is the true number with a certain confidence interval. Therefore, $p < 0.001$ indicates a 99.999% probability that the number did not occur by chance. "p" values this low are rarely seen in clinical medical studies.

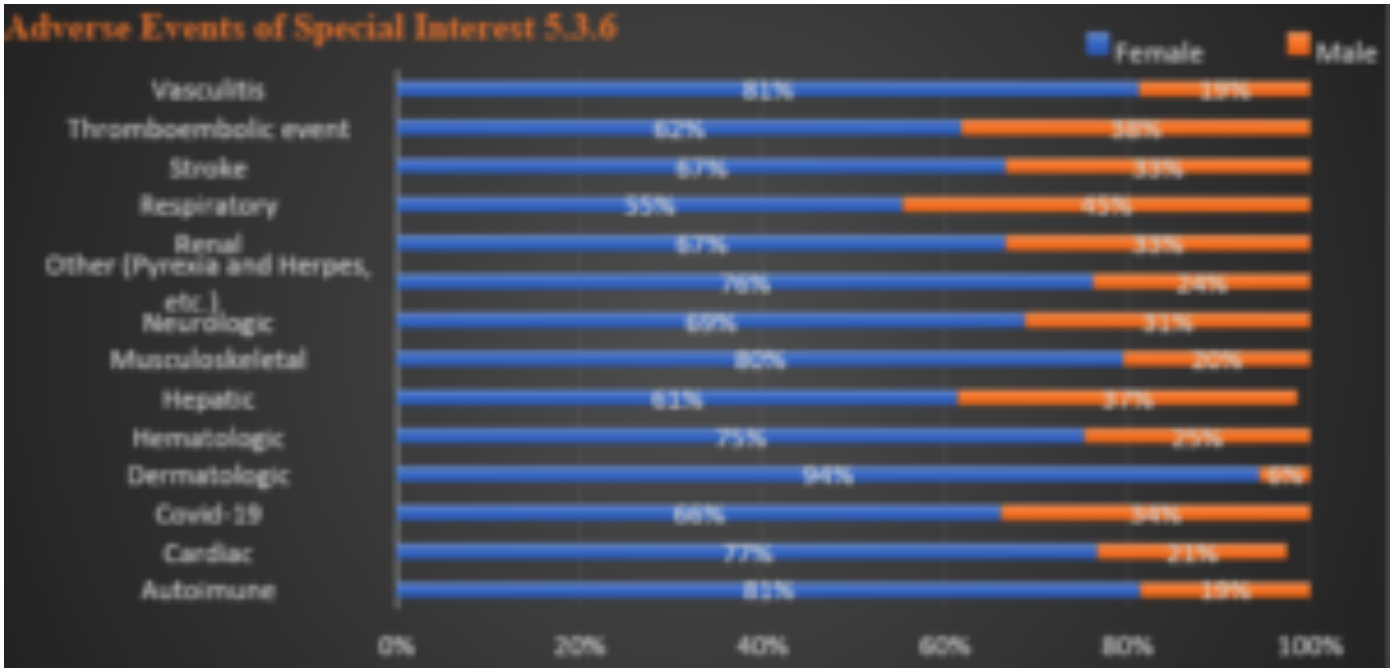
Chart 1: Female/Male Ratio in 39,096 Subjects



This trend follows through Table 7 (AESI), from 5.3.6 Reissue. Chart 2 shows the female-to-male ratio as percentages for each organ system as reported. Note that females substantially outnumber males in all categories and by more than a factor of three overall.

There is no category in which the number of cases for males outnumber females. Statistical significance exists at $p < 0.05$ in comparison of the rates of particular types of AEs in females versus males. Hematologic, Dermatologic, Other (Pyrexia and Herpes), Renal and Vasculitis all appear as exceptions with p values > 0.05. **Note**: Dermatologic was evaluated using Fisher exact test due to small sample size, $p = 0.093$.

Chart 2: Organ System Detail



Sex Differences Example 2: Appendix 2.1

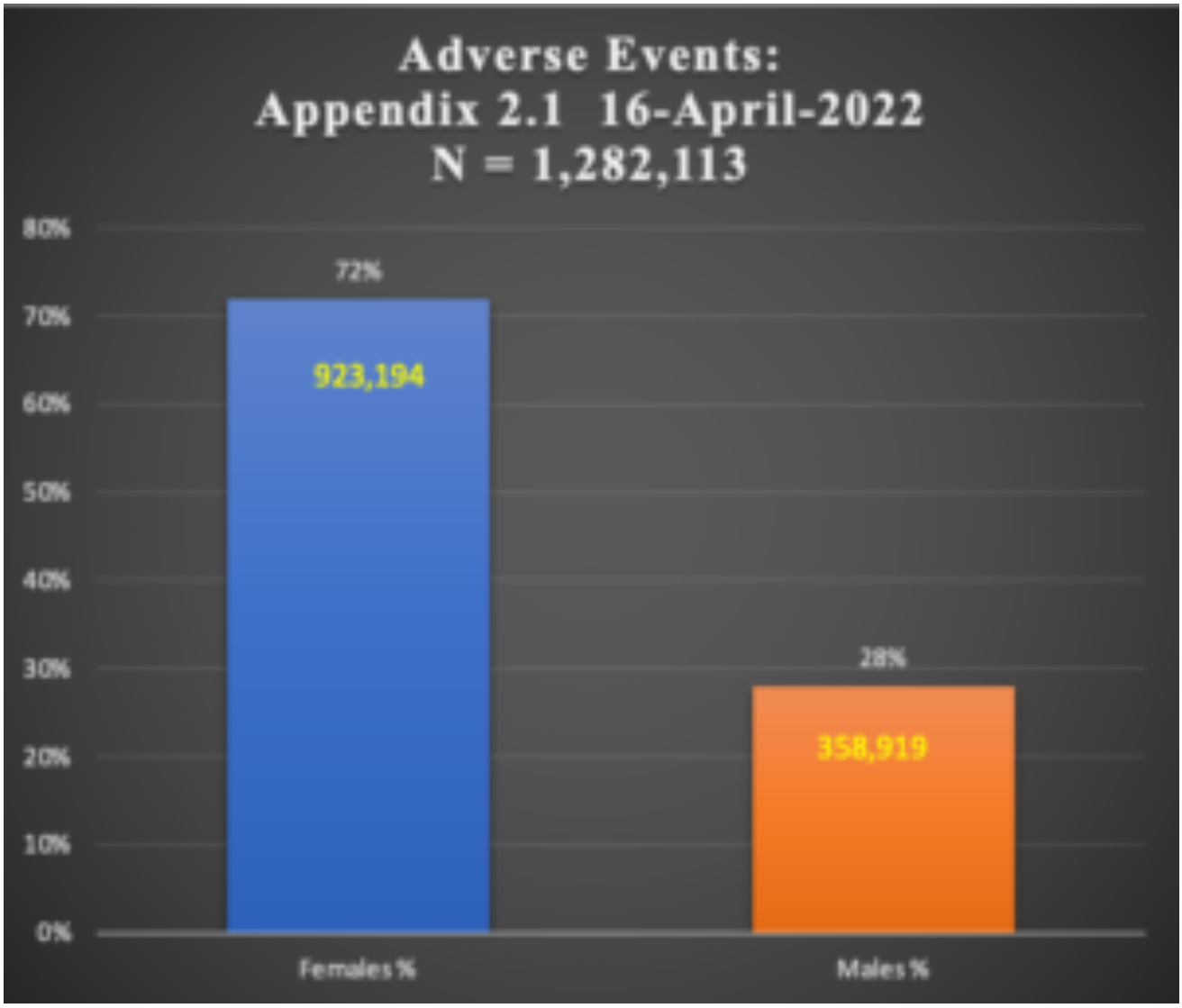
A second large series of Adverse Events associated with Pfizer's BNT162b2 vaccine document trove, Appendix 2.1, recently surfaced following a FOIA request from the Australian Therapeutic Goods Administration (TGA) and consists of a 170-page document that tallies Adverse Events by diagnosis in 1,348,079 subjects (i.e., patients). The sex was known in 1,282,113 cases – 923,194 women (72% of those with known sex and 68% of total series including unknown sex) and 358,919 men. Data capture ended on April 15, 2022.

The total number of Adverse Events reported in this document is 4,563,770 for an average of 3.4 AEs per case. The disproportionate representation of AEs in females presents again strongly here, as it did in Pfizer's 5.3.6 Reissue document.

Table 2: Female:Male Difference in 1,282,113 Cases of Adverse Events

Study	Females %	Males %	Females	Males	N =	
Appendix 2.1 16-April-2022	72%	28%	923194	358919	1282113	

Chart 3: Female:Male Comparison in AEs Subjects

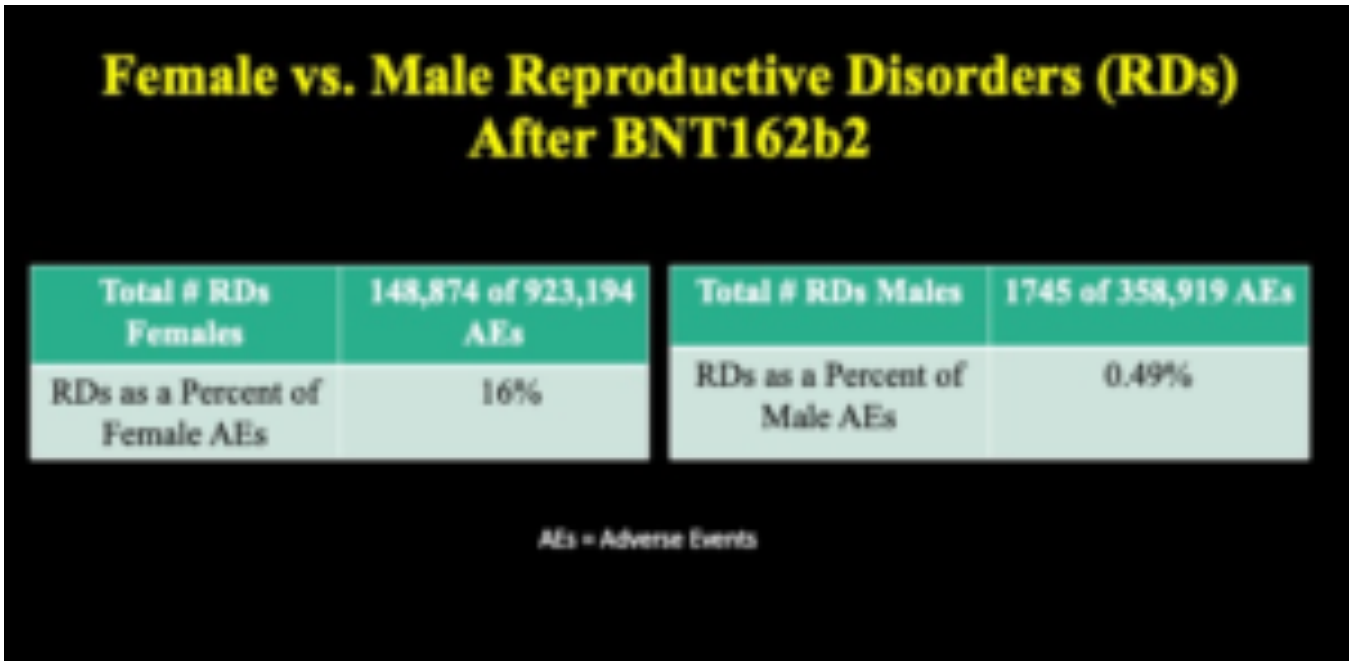


Adverse Events occur two and a half times more in women than men as shown in Chart 3 above. This is the same pattern seen in the earlier reporting of a smaller series from Document 5.3.6, $p < 0.001$.

Chart 4 illustrates this same disparity in the specific data referable to female and male reproductive organ and organ function disorders with much higher absolute numbers for women as well as in terms of percent of adverse events.

A striking difference is shown here with 148,874 women reporting Reproductive System AEs contrasted with only 1,745 males, $p < 0.001$.

Chart 4: Reproductive Organ and Function Sex Differences

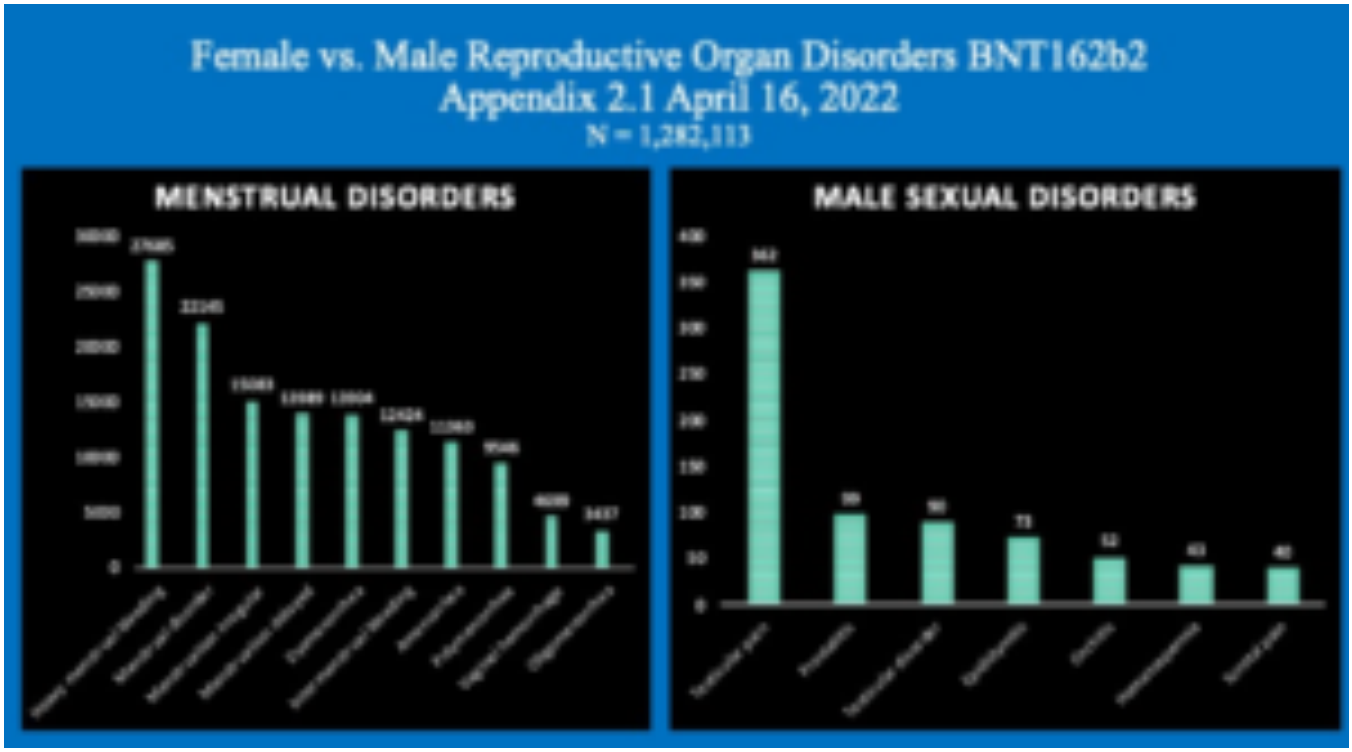


As seen in Chart 5, below left, females appear to have fewer diagnostic categories than males but only because there are so many for women that a charting of them is too busy if all are plotted.

For comparison of the sexes see Appendix 2 (females) and Appendix 3 (males) that list the reported reproductive organ and organ function disorders by sex following injection of Pfizer's BNT162b2. This tally lists diagnoses with reporting frequency of ten or more.

Chart 5 shows the numbers of the just the top ten *menstrual* dysfunctions contrasted with the much smaller number of reproductive issues in men.

Chart 5: Menstrual Disorders compared with Male Reproductive Disorders



Why do Women Have So Many More Adverse Events than Males?

No immediate answer to this question exists. However, the signal is strong.

Is there some distortion in the reporting mechanism that might explain such a wide difference? Perhaps. Is there some kind of systematic reporting bias? We can only speculate at present.

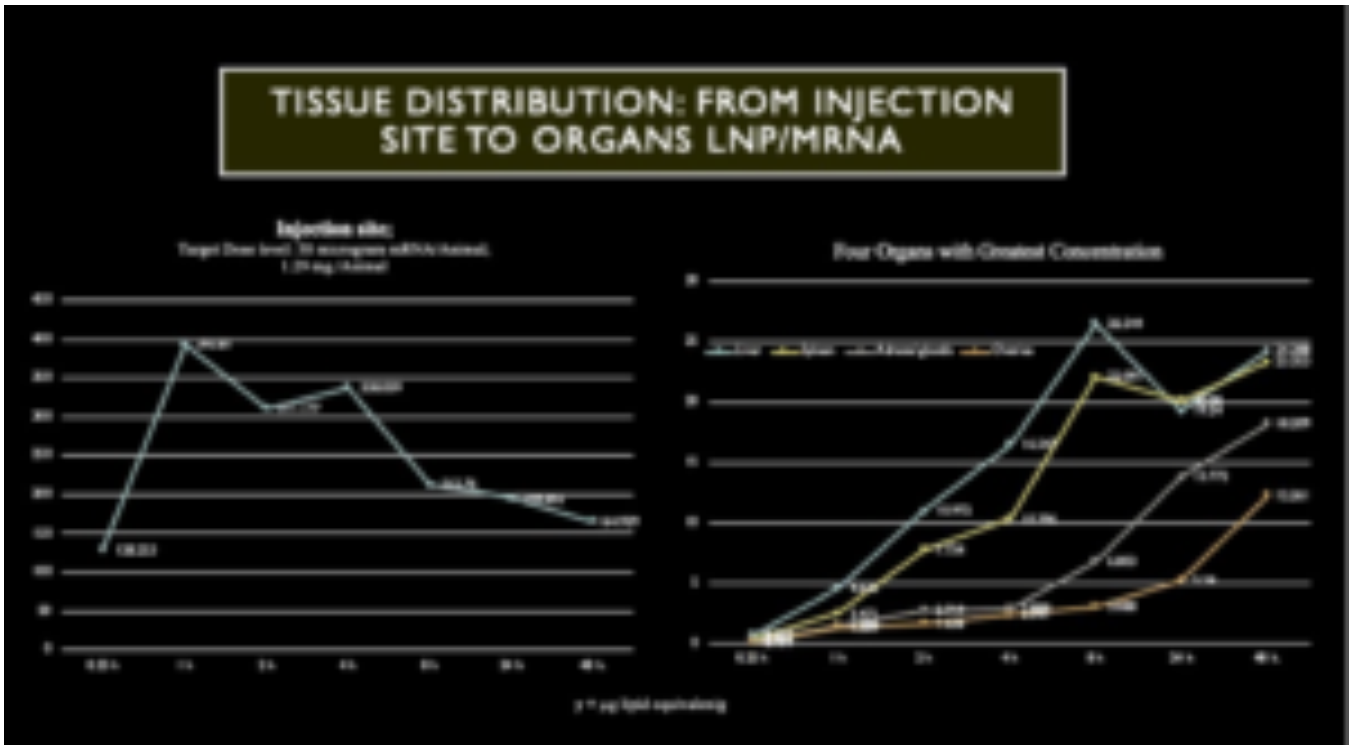
Alternatively, are there true sex differences in reaction to Pfizer's LNP/mRNA injections? Are women more prone to having complications after receiving Pfizer's BNT162b2 vaccine? Perhaps. Is there something about the LNP/mRNA concentration in ovaries that leads to production of more mRNA transcribed Spike or Spike-related proteins that have been shown to be toxic in multiple studies.

We have seen from the preclinical animal studies, Chart 6 following, that ovaries are one of the top four organs as far as concentration of LNP/mRNA is concerned. But, unfortunately, this study in Wistar Han Rats only ran for two days and no longer-term studies were performed. Furthermore, the ovaries – like liver, spleen and adrenal glands – had LNP/mRNA concentrations that were steeply rising at the time of animal sacrifice.

Had autopsies had been performed in a systematic manner following widespread human inoculation in individuals dying in the weeks following injection of Pfizer's BNT162b2, we may have had the answer by now and would certainly know more about gross and microscopic changes occurring in organs following the injection. Spike and related protein levels in the various organ systems would be of great interest.

Chart 6 illustrates deposition of LNP/mRNA at the injection site, left chart, followed by rapid dissemination throughout the body with concentration in four organs, liver, spleen, adrenal glands and ovaries, right chart.

Chart 6: Distribution of LNP/mRNA in Wistar Han Rats

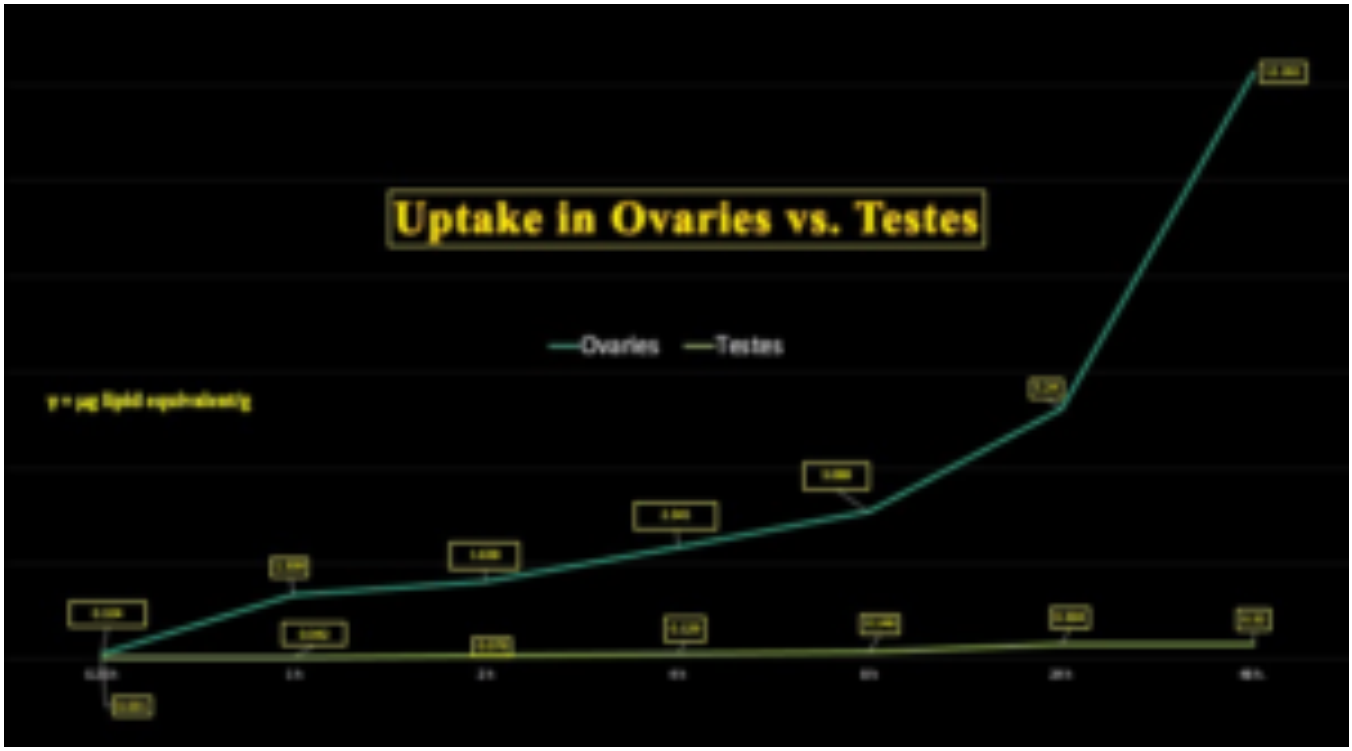


LNP/mRNA concentrates in ovaries as shown in Chart 6 illustrating data from preclinical studies performed in Wistar Han Rats. Note: The X-axis is nonlinear in Charts 6 and 7. Interpret the data accordingly.

Caution is needed here as animal studies may be misleading. There is such a thing as species-specific reactions, and humans may have different findings.

Chart 7 illustrates the disparity between ovaries and testes with respect to LNP/BNT162b2 uptake showing more than 38 times more concentration in ovaries than testes, as shown in these animal studies.

Chart 7: Tissue Concentration of LNP/mRNA Ovaries vs. Testes



Why do ovaries concentrate lipid nanoparticles and mRNA contained therein so much more effectively than testes?

And does this account for the large disparity in the incidence of Adverse Events and Adverse Events of Special Interest following injection of BNT162b2 in women as opposed to men?

Or are these differences in AEs overall and with respect to the dysfunction in the Reproductive Systems specifically a result of some methodological quirk?

We cannot definitively answer that question at present. For now, we must interpret these data as showing women are at increased risk for Adverse Events from Pfizer's LNP/mRNA product than are men, both in terms of many or all organ systems but especially with respect to reproductive organ systems and their functions.

Assuming this differential is caused by the disproportionate impact of BNT162b2 on women and their reproductive systems and organs, the implications could be profound.

Appendix 1: Female Reproductive AEs Following Inoculation with BNT162b2

148,874 reproductive organ AEs occurred in women which represents ~16% of the total number of Adverse Events in women. The list below gives the diagnoses reported 10 or more times.

Total AEs N =	**923194**
Heavy menstrual bleeding	27685
Menstrual disorder	22145
Menstruation irregular	15083
Menstruation delayed	13989
Dysmenorrhea	13904
Intermenstrual bleeding	12424
Amenorrhea	11363
Polymenorrhea	9546
Breast pain	4800
Vaginal hemorrhage	4699
Oligomenorrhea	3437
Hypomenorrhea	2643
Postmenopausal hemorrhage	2456
Abortion spontaneous	1809
Breast swelling	1339
Menstrual discomfort	1199
Premenstrual syndrome	998
Breast tenderness	792
Menometrorrhagia	632

Adnexa uteri pain	609
Premenstrual pain	585
Breast enlargement	483
Vaginal discharge	480
Breast discomfort	443
Mastitis	392
Ovulation pain	347
Endometriosis	337
Menstrual cycle management	308
Anovulatory cycle	273
Uterine pain	270
Abnormal withdrawal bleeding	265
Uterine hemorrhage	231
Vulvovaginal pain	191
Ovulation delayed	181
Premature baby	181
Vulvovaginal mycotic infection	173
Breast cancer	147
Fetal death	147
Fetal growth restriction	124
Vulvovaginal candidiasis	122
Breast cyst	115
Genital hemorrhage	115
Breast edema	113

Abnormal uterine bleeding	100
Pelvic venous thrombosis	98
Labor pain	95
Uterine leiomyoma	91
Polycystic ovaries	82
Breast discharge	71
Vulvovaginal pruritus	71
Breast disorder	68
Uterine contracture during pregnancy	68
Ectopic pregnancy	67
Premature labor	64
Morning sickness	62
Vaginal infection	60
Vulvovaginal discomfort	59
Abortion	58
Premature menopause	58
Vulval ulceration	56
Stillbirth	56
Vulvovaginal dryness	54
Coital bleeding	46
Ovarian cyst rupture	44
Premature delivery	44
Endometrial thickening	42
Genital burning syndrome	42

Adenomyosis	41
Breast abscess	41
Fetal heart rate abnormal	41
Menarche	40
Premenstrual headache	40
Uterine contractions abnormal	40
Breast induration	39
Premature rupture of membranes	37
Uterine polyp	37
Vulvovaginal swelling	37
Abortion induced	36
Uterine inflammation	36
Vulval hemorrhage	34
Pelvic inflammatory disease	33
Pregnancy	32
Pelvic discomfort	30
Premature menarche	27
Premature ovulation	27
Breast hematoma	26
Infertility female	26
Postpartum hemorrhage	26
Uterine disorder	26
Pelvic hemorrhage	25
Noninfective oophoritis	23

Vaginal ulceration	23
Dyspareunia	22
Ovarian disorder	22
Unintended pregnancy	22
Vaginal order	22
Vulvovaginal inflammation	21
Breast cancer	20
Breast disorder female	20
Hemorrhagic ovarian cyst	20
Placental disorder	20
Gestational diabetes	19
Abortion early	19
Endometrial disorder	18
Nipple inflammation	18
Endometrial hyperplasia	18
Ovarian hemorrhage	17
Ovarian failure	16
Vulvovaginal erythema	16
Ovarian vein thrombosis	15
Polymenorrhagia	15
Threatened labor	14
Fibrocystic breast disease	13
Ovarian enlargement	13
Uterine enlargement	13

Cervix hemorrhage uterine	12
Breast atrophy	11
Breast hemorrhage	11
Breast neoplasm	11
Cesarean section	11
Cervical dysplasia	11
Pelvic girdle pain	11
Vaginal disorder	11
Vulval disorder	11
Bartholin’s cyst	10
Decidual cyst	10
Fetal cardiac disorder	10
Fetal growth abnormality	10
Fetal vascular malperfusion	10
Vaginal cyst	10
Small for dates baby	10
Vaginal cyst	10

Appendix 2: Male Reproductive Disorders Following Inoculation with BNT162b2

1,745 reproductive organ AEs were reported in men which represents 0.49% of the total number of Adverse Events in men. AEs list occurred 10 or more times.

Males	
Total AEs =	**358919**
Testicular pain	362
Prostatitis	99
Testicular disorder	90
Epididymitis	73
Orchitis	52
Hematospermia	43
Scrotal pain	40
Penile pain	31
Penis disorder	31
Benign prostatic hypertrophy	26
Penile swelling	25
Scrotal swelling	24
Erection increased	23
Testicular disorder	22
Orchitis noninfective	20
Ejaculation disorder	18
Ejaculation failure	18
Prostatomegaly	18
Priapism	17

Testes discomfort	16
Spontaneous penile erection	15
Penile edema	13
Prostatic disorder	13
Penile hemorrhage	11
Penile erythema	10
Penile vein thrombosis	10
Scrotal erythema	10

Report 35: "Despite Incomplete Safety Trials, the Food and Drug Administration (FDA) Grants Full Approval to Pfizer-BioNTech's COMIRNATY® for Adolescents 12-15 Years of Age" by Chris Flowers, MD based on findings by Team 1 physician and investigator, C.T.

Without a completed safety study or expert committee review, the FDA issued a supplemental Biologics License Application ("sBLA") approval letter granting full FDA approval to Pfizer-BioNTech's COMIRNATY® COVID-19 mRNA vaccine for use in children ages 12-15. This was done even though safety study completion, on which approval should be based, will not be completed until May 31, 2023. [https://www.fda.gov/media/159727/download and https://www.pfizer.com/news/announcements/pfizer-and-biontech-announce-us-fda-approval-their-covid-19-vaccine-comirnatyr] Additionally, the approval was issued even though COMIRNATY is still not available in the United States. [DeMasi, Maryanne. "Is Pfizer's FDA-approved COMIRNATY Vaccine Available in the US?" *Brownstone Institute*, May 22, 2022. https://brownstone.org/articles/is-pfizers-fda-approved-comirnaty-vaccine-available-in-the-us/] Thus, the FDA has approved a commercial drug for children without appropriate evidence of safety.

There was no emergency to approve this vaccine without a full safety evaluation. The only vaccine currently available for American children is Pfizer's Emergency Use Authorization (EUA) drug, a drug that is legally distinct from COMIRNATY® per the FDA. [Johnson, Ron. "Sen. Johnson Continues to Press the FDA, Pfizer, BioNTech on Transparency and Politicization of Vaccine Approval Process." *Ron Johnson Senator from Wisconsin*, Senate.gov, 8 Oct. 2021, https://www.ronjohnson.senate.gov/2021/10/sen-johnson-continues-to-press-the-fda-pfizer-biontech-on-transparency-and-politicization-of-vaccine-approval-process] The FDA has approved COMIRNATY® over a year *before* the results of the safety data will be known. In short, the FDA approved a drug for children without complete safety data and without the participation of an expert panel. Moreover, it approved a drug for children that is not currently available in the U.S. and has no known date when it will be available. [DeMasi, Maryanne. "Is Pfizer's FDA-approved COMIRNATY Vaccine Available in the US?" *Brownstone Institute*, May 22, 2022. https://brownstone.org/articles/is-pfizers-fda-approved-comirnaty-vaccine-available-in-the-us/] Therefore, children are still receiving an experimental vaccine with the original Wuhan Alpha spike protein mRNA, which is outdated and known to have serious adverse side effects.

The FDA's mission statement purports to protect residents of the United States from harms, including those from medications, from the products that it regulates. [https://mission-statement.com/fda/] So why did the FDA skip the standard safety steps to approve COMIRNATY® for adolescents before its level of safety was fully understood? To answer this, one must look at what has happened and what has been omitted.

Background

In a new low for the agency charged with keeping Americans safe and ensuring the drugs it regulates are effective, the FDA gave full approval on August 23, 2021, to Pfizer-BioNTech for its BLA STN 125742/0 mRNA vaccine, also known as COMIRNATY®, to be used in adolescents 16 years of age and older. The FDA issued a post-marketing requirement related to this approval. The associated Pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY® in children 12-15 years of age is due to be completed in May 2023, with final report submission due in October 2023. [https://www.fda.gov/media/151710/download, p. 5.] It is noteworthy that the initial approval letter from August 2021 approved the use of COMIRNATY in children 16 years and older, despite increasing evidence of serious side effects, including myocarditis. [https://www.fda.gov/media/151710/download, p. 5.]

Can we trust the data from this trial?

There has been extensive criticism of this trial since November 2021, and of the FDA's reliance on it for granting Emergency Use Authorizations (EUAs) for vaccinating young children. [Shir-Raz, Yaffa, M.D. "Serious violations and manipulations of trial protocol: How Pfizer obtained FDA emergency authorization for children." *AFLDS Frontline News*, November 23, 2021. https://americasfrontlinenews.com/post/serious-violations-and-manipulations-of-trial-protocol-how-pfizer-obtained-fda-emergency-authorization-for-children] The efficacy claims, for instance, are based on data from before Delta and before Omicron. Children's Health Defense also sent a letter to the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) explaining the problems with the children's trials. [https://childrenshealthdefense.org/wp-content/uploads/CHD-Letter-to-FDA-VRBPAC-2022-06-10.pdf]

Are there not pre-existing protections for children with higher standards than protections for adult medications?

Yes. The Pediatric Research Equity Act (PREA) "requires the conduct of pediatric studies for certain drug and biological products." [https://www.fda.gov/drugs/development-resources/pediatric-research-equity-act-prea] It requires biologics licensing applications (BLAs), or supplements to applications, for any new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to contain a "pediatric assessment" showing that it is safe for children, unless the applicant has obtained a waiver or deferral (reference section 505B(a) of PREA).

What does the deferred language mean in the FDA approval letter?

The FDA approval allowed for "deferral" of the usual testing process. "If a deferral has been granted, the pediatric assessment will be due on or before the date specified by the Agency (section

505B(a)(3) of PREA).” [https://www.fda.gov/media/151710/download and https://www.fda.gov/media/72274/download]

Although the trial purportedly showed 100% effectiveness and that the drug was tolerated well, the safety of patients in the trial was not fully established prior to the FDA’s approval of this injection for minors. All participants in the trial needed to be monitored for long-term protection and safety for an *additional two years* after their second dose. That is why data will continue to be collected until May 2023, and a final report will be submitted to the FDA by October 31, 2023. [https://www.fda.gov/media/151710/download, p. 5.] So, the approval for the Pfizer mRNA injection for minors short-circuited this process.

Under those circumstances, how can we ensure this vaccine’s long-term safety to our children?

We cannot ensure long-term safety under this truncated process. The trial that was used only follows the candidates within the trial itself, and the FDA’s only requirement of Pfizer, in this case, was that they present their own data. Thus, there is no reference to any adverse events that are subsequently reported in the Vaccine Adverse Events Reporting System (VAERS), which has been shown to only report 1% of vaccine injuries, a gross level of underreporting. [AHRQ’s Lazarus Report, 2011, https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.] Under these circumstances, there is no mechanism by which the FDA can look at the totality of the data in terms of harms to children over time.

What could the FDA do to provide safety during medical interventions, especially in pediatric patients?

The safety of a product should be paramount in infants and children, with proper observation and reporting of serious adverse events, and a longer time should be allocated for this to happen prior to any drug approval, as is usually the case.

The Pfizer pediatric trial does not end for nearly another year, and yet the FDA committee decided that completion of such longer-term follow-up did not need to be a prerequisite to licensure unless warranted by a specific safety concern. [https://www.fda.gov/media/159727/download and https://www.pfizer.com/news/announcements/pfizer-and-biontech-announce-us-fda-approval-their-covid-19-vaccine-comirnatyr] By truncating the timeline of the trials and restricting the data observed, they did not look for and, thus, chose not to find safety concerns.

Call to Action

Americans must demand that the VAERS database be improved, and people should be strongly encouraged to report adverse events directly into its online portal. The database findings

should be reviewed by the VRBPAC, alongside any trial data from a pharmaceutical company. Additionally, no drug should be approved for use in children without fully completed, submitted, and evaluated safety studies over the appropriate length of time.

Potentially ALL American children aged 12-15 are affected, as this is a full commercial approval. The stakes could not be higher for the health and wellbeing of our next generation of Americans.

Report 36: "Data Do Not Support Safety of mRNA COVID Vaccination for Pregnant Women" by Robert W. Chandler, MD, MBA – Team 5.

Commentary on Preliminary Findings of "mRNA Covid Vaccine Safety in Pregnant Persons" as Reported by the Centers for Disease Control and Prevention and the Food and Drug Administration, June 17, 2021, *New England Journal of Medicine*.

Currently, the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP), American College of Obstetricians and Gynecologists (ACOG), and the American Academy of Pediatrics (AAP) recommend that Covid-19 vaccines should not be withheld from pregnant women. The following analysis will show that no accurate, reliable scientific data were collected; and, thus, it is not possible to provide useful information about the risks to pregnant women and their babies from Covid mRNA vaccines. Because of this, medical and public health organizations are remiss in their duties to protect the health and well-being of patients when they endorse the use of mRNA vaccines in pregnant women. [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html, https://www.cdc.gov/vaccines/hcp/acip-recs/rec-vac-preg.html, https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care, and https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/about-the-covid-19-vaccine-frequently-asked-questions/.]

I. Context:

This article was undertaken as part of a widespread review of Food and Drug Administration (FDA)-released Pfizer documents concerning their experimental lipid nanoparticle plus messenger ribonucleic acid gene (LNP/mRNA) therapy drug, BNT162b2.

On January 6, 2022, Judge Mark T. Pittman of the United States District Court in the Northern District of Texas ordered the release of the Pfizer clinical trial documents. [https://www.sirillp.com/wp-content/uploads/2022/01/ORDER_2022_01_06] The FDA had requested that the documents be sealed for 75 years.

Pfizer completed Phase 3 trials of BNT162b2 in fall of 2020 and submitted its application for an Emergency Use Authorization (EUA) to the FDA on November 20, 2020. On December 11, 2020, the FDA issued an Emergency Use Authorization (EUA). Widespread distribution and mass inoculation began shortly afterward. [https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19]

Moderna received approval for their product, mRNA-1273, along a similar timeline. [https://www.aha.org/2020-12-19-special-bulletin-summary-fda-emergency-use-authorization-modernas-covid-19-vaccine]

The *New England Journal of Medicine* (*NEJM*) published a research article, Shimabukuro, et al., on June 17, 2021, (online publication) authored by 21 affiliates of the CDC and FDA on behalf of the 47-member CDC and FDA Pregnancy Registry Team entitled "Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons." [https://www.nejm.org/doi/full/10.1056/NEJMoa2104983] *NEJM* first published this on April 21, 2021, and updated it on September 8, 2021. However, the April and September versions are not available online, despite *NEJM* stating, "This article was published on April 21, 2021, and updated on September 8, 2021, at NEJM.org." [https://www.nejm.org/doi/full/10.1056/NEJMoa2104983]

This study reported results of 35,691 pregnant women, entered into the V-safe Registry maintained by the CDC, who received at least one dose of either the Pfizer/BioNTech or Moderna Covid-19 drug during the ten-week period from December 14, 2020, through February 28, 2021. [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html]

Results from the Vaccine Adverse Event Reporting System (VAERS) were also queried, and the results are presented.

Shimabukuro, et al. identify the then and now current CDC policy regarding use of new SARS-CoV-2 Spike encoding genetic products from Pfizer and Moderna in pregnant women:

> The Centers for Disease Control and Prevention (CDC) and ACIP, in collaboration with the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, have issued guidance indicating that Covid-19 vaccines *should not be withheld* from pregnant persons. *Italics added.*
>
> [https://www.nejm.org/doi/pdf/10.1056/NEJMoa2104983?articleTools=true, p. 2274, and https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care.]

This article focuses on the basis of this recommendation in light of the CDC and FDA documentation presented in Shimabukuro, et al.

II: Registry Data and Data Mining

A registry, one of the scientifically weakest clinical research tools, ranks far below the gold standard randomized, double-blinded, tightly controlled study of at least two years duration or a prospective tightly controlled matched subject study.

SAP, a competitor to SAS the well-regarded maker of the statistical package used by the CDC and FDA on this project, notes the following about data mining:

> "With masses of new data, there are also masses of incomplete, incorrect, misleading, fraudulent, damaged, or just plain useless data. The tools can help sort this all out, but the users must be continually aware of the source of the data and its credibility and reliability."
> [https://www.sap.com/insights/what-is-data-mining.html]

Data professionals often refer to this as "GIGO" or "garbage in, garbage out." A registry can be used to detect signals, but it certainly does not generate robust, high-quality scientific data.

III. Methodology

Study samples reported in the Shimabukuro, et al. report came from two databases.
#1: The V-safe Surveillance System and Pregnancy Registry is a voluntary, smartphone-based surveillance system maintained by the CDC. Participants agree to receive periodic emails to which they respond. [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html]
One estimate puts the rate of participation in V-safe at about five percent of all those given the LNP/mRNA drug. [V-safe COVID-19 vaccine pregnancy registry. *Atlanta: Centers for Disease Control and Prevention*. May 3, 2021. (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html).]

From V-safe, participants were contacted and entered into a second registry, the Pregnancy Registry, from which data for this report were drawn. Those managing the Registry planned to collect data for 12 months.

#2: The second registry used was the Vaccine Adverse Event Reporting System (VAERS), a voluntary reporting system maintained by the CDC and FDA that was established 30 years ago to monitor side effects of vaccines. [https://vaers.hhs.gov/] The CDC verifies VAERS entries.

Diversity of opinion exists as to what percentage of actual adverse events (AEs) the VAERS reporting comprises – from a single-digit Under Reporting Factor (URF) of one to upwards of 40-plus percent. Overreporting is less likely given the verification process. The reader should keep this URF range of 1 to over 40 in mind for any VAERS data.[https://vaersanalysis.info/2021/12/13/using-cms-whistleblower-data-to-approximate-the-under-reporting-factor-for-vaers/ and https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf]

This article will also make reference to a third database maintained by Pfizer as reported in "Confidential Document 5.3.6." [https://robertchandler.substack.com/p/pfizer-document-536-cumulative-analysis]

A. V-safe/Pregnancy Registry Data
Outcomes were assessed in terms of comparison of reactogenicity in pregnant and non-pregnant women aged 16-54 years, as well as pregnancy outcomes.

Reactogenicity is a concept applied to vaccines and includes early reaction to drug products such as pain at the injection site, fever, other short-term signs and symptoms. [https://pubmed.ncbi.nlm.nih.gov/31583123/]

Reactogenicity differs from Adverse Events (AEs) and Adverse Events of Special Interest (AESI), which focus on specific categories of events and specific diagnoses by function and or organ system. Pregnancy outcomes (Shimabukuro, et al., https://www.nejm.org/doi/pdf/10.1056/NEJMoa2104983?articleTools=true, p. 2275.) in the Pregnancy Registry were assessed in a subset of completed pregnancies in terms of spontaneous abortion (loss of fetus in the first 20 weeks, also called 'miscarriage'), stillbirth (loss of fetus after 20 weeks), preterm birth, congenital anomalies, small size for gestational age and neonatal death. Multiple factors cause the loss of a fetus, and such loss occurs decreasingly as a function of duration of gestation. The miscarriage rate is highest in the first six weeks, and most fetal loss occurs in the first trimester. [https://obgynkey.com/chapter-6-first-trimester-abortion/https://my.clevelandclinic.org/health/diseases/9688-miscarriage#diagnosis-and-tests Journal of Epidemiology and Community Health 38(2):143-8] [https://www.nejm.org/doi/10.1056/NEJM198807283190401?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed]

Data are entered and database queries return results from the system. Each query can return data from different subjects. *It must be understood that the numbers returned from each query likely represent a unique set of subjects making comparisons across queries problema*tic.

Contrast this process with a cohort study (one that takes in a predetermined number of subjects and actively follows them prospectively to completion) that produces a complete data set for all or most of those enrolled in the study. Data from this more robust type of study are very limited.

B. VAERS Data
"VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA. VAERS is not designed to determine if a vaccine caused a health problem but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. This way, VAERS can

provide CDC and FDA with valuable information that additional work and evaluation is necessary to further assess a possible safety concern." [https://vaers.hhs.gov/about.html]

Analysis of VAERS reporting included Adverse Events (AEs) that are both pregnancy and non-pregnancy related.

IV. Outcomes:

There were 35,691 pregnant women entered into CDC's V-safe COVID-19 Pregnancy Registry system during the first two and a half months after EUA. Remember that these almost 36,000 pregnant women may be just five percent of the total number of pregnant women injected with the LNP/mRNA drug as of February 28, 2021. If they represent only five percent, then the real total of pregnant women who received the drug would be close to 720,000.

Of the 35,691 cases 5,230 were contacted and offered enrollment in the Pregnancy Registry and a total of 3,958 agreed and qualified for further study.

Table 1: V-Safe Data Set

As of 3/30/2021 for data 12/14/2020 thru 2/28/2021		
From Table 1, Shimabukuro, et al.[3]		
mRNA + Pregnancy Cases	35691	
Pregnant at time of Injection	30887	
+ Pregnancy test after injection	4804	

Table 2 gives the summary statistics for the Pregnancy Registry.

Table 2: Pregnancy Registry

Pregnant at or shortly after Injection	5230
Unreachable	912
Declined	86
Did not meet inclusion criteria	274
Eliminated	1272
Net	**3958**

These 3,958 pregnant women were the subjects of further analysis, but here is where the caution from SAS applies. *The numbers reported in each category may refer to results of a data query*

rather than unique individuals followed through various cuts. This is important in coming to an understanding of what exactly is being reported in Shimabukuro, et al.

A. Spontaneous Abortion Rate (SABR)
Spontaneous abortion does not include medically induced loss of fetus or stillbirths. [https://www.emedicinehealth.com/what_are_abortion_and_miscarriage/article_em.htm]

Of the 3,958 pregnant women entered into the v-safe pregnancy database, 1,132 cases received LNP/mRNA drugs during their first trimester and another 1,714 in their second trimester totaling 2,846 subjects injected during the first 24 weeks after conception, per Table 3. [https://www.nejm.org/doi/pdf/10.1056/NEJMoa2104983?articleTools=true, p. 2279.]

There were 2,846 combined first and second trimester subjects representing 72% of those receiving LNP/mRNA during pregnancy who were entered into the Pregnancy Registry and 7% of the entire sample of 35,691 pregnant women receiving LNP/BNT162b2. From authors' Table 3, page 2279 [https://www.nejm.org/doi/pdf/10.1056/NEJMoa2104983?articleTools=true]:

Timing of first eligible dose			
Periconception: within 30 days before last menstrual period	55 (2.6)	37 (2.0)	92 (2.3)
First trimester: <14 wk	615 (28.8)	517 (28.4)	1132 (28.6)
Second trimester: ≥14 and <28 wk	932 (43.6)	782 (42.9)	1714 (43.3)
Third trimester: ≥28 wk	533 (25.0)	486 (26.7)	1019 (25.7)
Missing data	1 (<0.1)	0	1 (<0.1)

Only 827 subjects out of the 3,958 cases enrolled in the Pregnancy Registry completed pregnancy during the study period. Random selection cannot be assumed based on information provided. This represents twenty-one percent of the group entered into the pregnancy registry and 2.3% of the initial group of 35,691 pregnant women drawn from the total pool**.** *827 represents about 0.001% of the estimated total number of pregnant women injected with LNP/mRNA in the first 10 weeks following EUA*.

The most profound change to the fetus occurs in the first trimester, and spontaneous abortion rates are much higher during this phase.

Therefore, pregnant women receiving LNP/mRNA during their first trimester are of special interest in terms of spontaneous abortion, prematurity, small size for gestational age, congenital anomalies, and neonatal death.

Caution: Multiple attempts have been made to calculate rates of spontaneous abortion from these data.

Four determinations of the rate of spontaneous abortion after LNP/mRNA treatment in pregnant women will be illustrated. A fifth, referred to as an MSU (Make Stuff Up) Analysis, will be addressed in a subsequent article.

1. V-safe Analysis 1:

Shimabukuro, et al. reported on spontaneous abortions as follows:

> "Among *827 participants* who had a completed pregnancy, the pregnancy resulted in a live birth in 712 (86.1%), in a *spontaneous abortion in 104 (12.6%)*, in stillbirth in 1 (0.1%), and in other outcomes (induced abortion and ectopic pregnancy) in 10 (1.2%). A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation (Table 4), and *700 of 712 pregnancies that resulted in a live birth (98.3%) were among persons who received their first eligible vaccine dose in the third trimester*."
> [https://www.nejm.org/doi/pdf/10.1056/NEJMoa2104983?articleTools=true, p. 2276.]

Here the authors' calculated a 12.6% rate of spontaneous abortion using 104 as the numerator and 827 as the denominator.

However, *this is a gross error* as spontaneous abortion refers to loss of the fetus during the first 20 weeks, and the *827* included *700 third trimester pregnancy cases*. So, using 827 as a denominator is *erroneous and misleading*.

Later attempts were made to retroactively change this number, but it remains in the June 17, 2021, online version of the article. [https://www.nejm.org/doi/full/10.1056/NEJMoa2104983] A September 8, 2021, editorial effort successfully deleted the calculation from Table 4 of the June 17, 2021, version as acknowledged in the *NEJM* on October 14, 2021, but the 12.6% figure remains in the text. [https://www.nejm.org/doi/full/10.1056/NEJMc2113516]

Additionally, *only 127 participants received LNP/mRNA* products during *the first and second* trimesters. Why lump first and second trimester cases together? The risk for spontaneous abortions is almost all in the first trimester.

2. V-safe Analysis 2:

Some have attempted to pull the first trimester cases out of the data to match these cases with the 20-week abortion group. Why not match the 20-week group with the 20-week spontaneous abortions? Great question.

Here is how Analysis 2 goes.

Authors' Table 4 reports 104 spontaneous abortions during the first 20 weeks. [https://www.nejm.org/doi/pdf/10.1056/NEJMoa2104983?articleTools=true, p. 2280.]

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	*no./total no. (%)*
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk[15-17] ‡	Not applicable	104
Stillbirth: ≥ 20 wk[18-20]	<1	1/725 (0.1)§

Table 2 below summarizes the data regarding the numbers of total pregnant women in V-safe, the number entered into the Pregnancy Registry and the number who complete their pregnancy. Given as well is the number of spontaneous abortions in the first 20 weeks.

Table 2: CDC Spontaneous Abortions

[Reference James Thorp, M.D.'s calculations in the comments section of https://pierrekory.substack.com/p/massive-miscarriage-rates-among-vaccinated]

	N	%
Pregnant women (PW) injected 12/14/2020-2/28/2021	35691	
PW Enrolled in Pregnancy Registry	3958	11.1%
PW Completing Pregnancy (CP)	827	2.3%
PW CP Inoculated during first two trimesters 24 wks. Or less	127	
Spontaneous abortions < 20 weeks	**104**	**82%**

A spontaneous abortion rate of 82% appears to be impossibly high compared with published rates of 10 to 20%. [https://www.mayoclinic.org/diseases-conditions/pregnancy-loss-miscarriage/symptoms-causes/syc-20354298]

The 104 mothers with spontaneous abortions are probably not from the same query pool as the 127, making this calculation erroneous as well.

To date, the raw data have not been made available even though this paper was published 14 months ago. Independent analysis and verification are therefore impossible.

Question	Authors' Response
Will the data collected for your study be made available to others?	No
Would you like to offer context for your decision?	Our goal is to make deidentified data publicly available, but the process is still under development. Data are not available to others at the time of publication.

[https://www.nejm.org/doi/suppl/10.1056/NEJMoa2104983/suppl_file/nejmoa2104983_data-sharing.pdf]

3. V-safe Analysis 3:

This analysis begins with the completed pregnancies as the rest of the figures above 827 in Table 2, i.e., 3958 and 35,691, are unchanged.

Completed pregnancies	827
Live births	712
1st and 2nd Trimester	12
3rd Trimester	700
Spontaneous abortions + Stillbirth	115
Spontaneous abortions before 13 weeks gestational age	96
Pregnant woman injected within 30 days before the first day of the last menstrual period or in the first trimester the first day	1224
No follow up through 20 weeks	905
Follow up through 20 weeks	319
Spontaneous abortions @<20 weeks	104
Spontaneous abortions @<20 weeks	**33%**

Unfortunately, this approach falls victim to the same flaw as in Analysis 2, multiple unique groups.

4. V-safe Analysis 4:

If one waited until the October 2021 update to read this paper, he or she would have been rewarded with the final analysis as contained in this bizarre statement:

No denominator was available to calculate a risk estimate for spontaneous abortions because at the time of this report, follow-up through 20 weeks *was not yet available for* 905 of the 1224 participants vaccinated within 30 days before the first day of the last menstrual period or in the first trimester. **Spontaneous abortions @<20 weeks Unknown**	

[https://www.nejm.org/doi/full/10.1056/NEJMx210016]

Bottom line: Computation of spontaneous abortion rate from V-safe Registry data does not *produce a reasonable estimate of the true rate of spontaneous abortion in women given LNP/mRNA products during pregnancy, particularly during the critical first 12 to 14 weeks.*

5. VAERS Registry Spontaneous Abortion Rate

Perhaps VAERS can help? Table 5 shows the results of the VAERS database query.
[https://vaers.hhs.gov/]

Table 5: VAERS

Pregnant women	221
Non pregnancy AEs	155
Pregnancy/Neonatal AEs	66
Pregnancy related AEs	
Spontaneous abortions (SAs)	46
1st Trimester SAs	37
2nd Trimester SAs	2
Unknown	7
Stillbirth	3
Premature membrane rupture	3
Vaginal bleeding	3

The authors do not provide the logic or terminology used to query the VAERS database *making verification of these numbers impossible*.

Unfortunately, not much can be concluded from this tiny, non-random sample of cases other than to note the potential harms of LNP/mRNA in pregnant women and their babies.

6. Pfizer Registry Abortion Rate

For comparison with V-safe and VAERS, there is Pfizer document "5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021" that reports Adverse Events in its own registry collected during the same time period covered by the CDC data and reports on spontaneous abortions in 28 completed pregnancies. [https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf and https://robertchandler.substack.com/p/why-do-females-have-more-adverse]

The trimester of the injection(s) was /were not given.

Altogether there were 270 pregnant women who received LNP/mRNA injections, but outcome was not known in 238 and 5 were in progress.

Table 3: Pfizer Spontaneous Abortions

Pregnancies with outcomes out of 270 PW	28	
Spontaneous abortion	23	82%

With 88% of the pregnant women unaccounted for and no information provided about injection date as a function of gestational age no reasonable estimate of spontaneous abortion rate can be made from these data.
Using the 720,000 estimate of the actual number of pregnant women receiving LNP/mRNA from the V-safe Registry in the first 10 weeks, these 28 cases represent a non-random sample of 0.00004% of the estimated total number of pregnant women given experimental gene products during the period from December 14, 2020, to February 28, 2021.

B. Pre-Term, Small Size and Congenital Anomalies.

Of the 724 live-born infants in the V-safe registry there were 60 of 636 preterm births, 23 of 724 small for gestational period and 16 of 724 with major congenital anomalies.

Table 4: Pre-Term, Small size and congenital anomalies.

Pre-Term Cases	60/636	636 vax before 37 wks.
Small size for gestational period	23/724	8%
Major congenital anomalies	16/724	3%

This data is virtually meaningless since there is no trimester data, no data about age at conception, comorbidities, number of prior pregnancies and births and so on.

C. Dose-Related Reactogenicity

Shimabukuro, et al. present the following reactogenicity data in their Table 2. [https://www.nejm.org/doi/pdf/10.1056/NEJMoa2104983?articleTools=true, p. 2277.]

Table 2. Frequency of Local and Systemic Reactions Reported on the Day after mRNA Covid-19 Vaccination in Pregnant Persons.*

Reported Reaction	Pfizer–BioNTech Vaccine		Moderna Vaccine		Total	
	Dose 1 (N=9052)	Dose 2 (N=6638)	Dose 1 (N=7930)	Dose 2 (N=5635)	Dose 1 (N=16,982)	Dose 2 (N=12,273)
	number (percent)					
Injection-site pain	7602 (84.0)	5886 (88.7)	7360 (92.8)	5388 (95.6)	14,962 (88.1)	11,274 (91.9)
Fatigue	2406 (26.6)	4231 (63.7)	2616 (33.0)	4541 (80.6)	5,022 (29.6)	8,772 (71.5)
Headache	1497 (16.5)	3138 (47.3)	1581 (19.9)	3662 (65.0)	3,078 (18.1)	6,800 (55.4)
Myalgia	795 (8.8)	2916 (43.9)	1167 (14.7)	3722 (66.1)	1,962 (11.6)	6,638 (54.1)
Chills	254 (2.8)	1747 (26.3)	442 (5.6)	2755 (48.9)	696 (4.1)	4,502 (36.7)
Fever or felt feverish	256 (2.8)	1648 (24.8)	453 (5.7)	2594 (46.0)	709 (4.2)	4,242 (34.6)
Measured temperature ≥38°C	30 (0.3)	315 (4.7)	62 (0.8)	664 (11.8)	92 (0.5)	979 (8.0)
Nausea	492 (5.4)	1356 (20.4)	638 (8.0)	1909 (33.9)	1,130 (6.7)	3,265 (26.6)
Joint pain	209 (2.3)	1267 (19.1)	342 (4.3)	1871 (33.2)	551 (3.2)	3,138 (25.6)
Injection-site swelling	318 (3.5)	411 (6.2)	739 (9.3)	1051 (18.7)	1,057 (6.2)	1,462 (11.9)
Abdominal pain	117 (1.3)	316 (4.8)	160 (2.0)	401 (7.1)	277 (1.6)	717 (5.8)
Injection-site redness	160 (1.8)	169 (2.5)	348 (4.4)	491 (8.7)	508 (3.0)	660 (5.4)
Diarrhea	178 (2.0)	277 (4.2)	189 (2.4)	332 (5.9)	367 (2.2)	609 (5.0)
Vomiting	82 (0.9)	201 (3.0)	77 (1.0)	357 (6.3)	159 (0.9)	558 (4.5)
Injection-site itching	103 (1.1)	109 (1.6)	157 (2.0)	193 (3.4)	260 (1.5)	302 (2.5)
Rash	20 (0.2)	18 (0.3)	22 (0.3)	18 (0.3)	42 (0.2)	36 (0.3)

* Shown are solicited reactions in v-safe participants 16 to 54 years of age who identified as pregnant and who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer–BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021.

There may be four different data samples represented here, which is a typical finding in a data mining project.

Tests of statistical significance were not performed on this data, but there appears to be a dose-related effect here that reinforces the observation from Pfizer pre-clinical and clinical trials that there is a dose-related response to LNP/mRNA. Dose-related adverse events are events that increase in frequency as the total amount of drug received increases and are of concern when considering the possible cumulative frequency and severity of AEs and AESI rates in a multiple booster program.

V. Omissions

The CDC authors neglected to mention the relevant omissions from the preclinical studies as reported in Pfizer confidential document ,"2.4 NONCLINICAL OVERVIEW," and listed below [https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf and https://robertchandler.substack.com/]:

A. Pre-Clinical Studies:

1. **Safety pharmacology:** "No safety pharmacology studies were conducted with BNT162b2 as they are not considered necessary for the development of vaccines according to the WHO guideline (WHO, 2005)." [https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p.14,¶2]

2. **Pharmacodynamic Drug Interactions:** "Nonclinical studies evaluating pharmacodynamic drug interactions with BNT162b2 were not conducted as they are not generally considered necessary to support development and licensure of vaccine products for infectious diseases (WHO, 2005)." [https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p. 14, ¶3]

3. **No pharmacokinetic studies:** were performed with BNT162b2 and "...are generally not considered necessary to support the development and licensure of vaccine products for infectious diseases (WHO, 2005, WHO, 2014)." [https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p. 17, ¶1]

4. **"***The protein encoded by the RNA in BNT162b2 is expected to be proteolytically degraded like other endogenous proteins.* RNA is degraded by cellular RNases and subjected to nucleic acid metabolism. Nucleotide metabolism occurs continuously within the cell, with the nucleoside being degraded to waste products and excreted or recycled for nucleotide synthesis. *Therefore, no RNA or protein metabolism or excretion studies will be conducted.*" [https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p. 20, ¶3]

5. **<u>Genotoxicity</u>:** "*No genotoxicity studies are planned for BNT162b2* as the components of the vaccine construct are lipids and RNA are not expected to have genotoxic potential (WHO 2005)." [https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p. 29, ¶3]

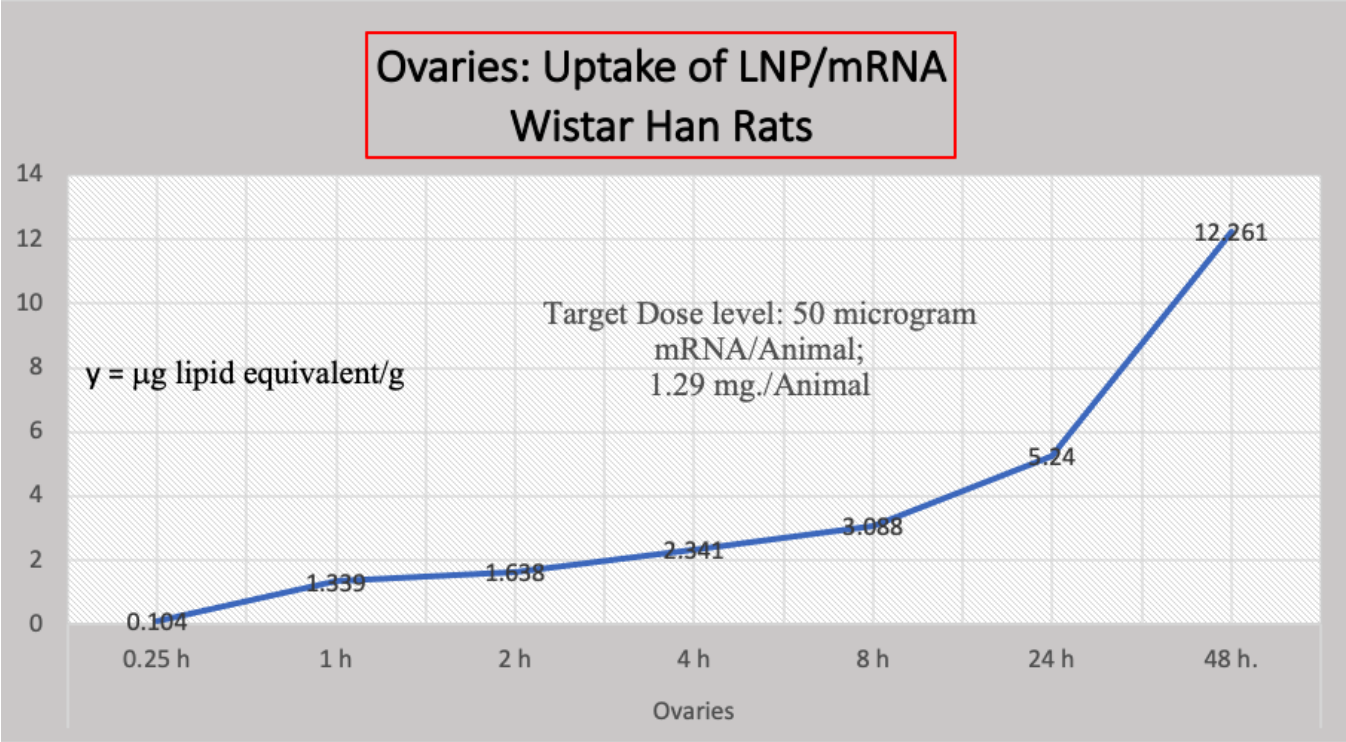
6. "*Carcinogenicity studies with BNT162b2 have* not *been conducted* as the components of the vaccine are lipids and RNA and are not expected to have carcinogenic or tumorigenic potential (WHO 2005)." [https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p. 29, ¶4]

These omissions were not mentioned in the Shimabukuro, et al. paper which was and continues to be used as reference for medical professionals charged with informing patients about the risks, benefits, and alternatives to never before used experimental gene therapy drugs that have the potential for gene modification, carcinogenesis, autoimmunity and a host of other medical problems both known and unknown.

It is now known that Spike proteins, mRNA and lipid nanoparticles are present for weeks to months, and possibly years, in human tissues, and the harms from these agents are being identified almost daily. [https://robertchandler.substack.com/p/bnt162b2-mrna-expresses-modified]

B. Biodistribution Data:
Another study *not mentioned* in the CDC document concerns the biodistribution of BNT162b2 that shows accelerating accumulation of LNP/mRNA in Wistar Han Rat ovaries, below Chart 4. [https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, pp. 15-20] *We have no such data in humans.*

Chart 4



Criticisms here have been that the dose may have not been suitable, that these biodistribution studies should have been run longer than 48 hours, and that animal studies can give misleading or erroneous results.

So, is it not possible to compress ten years of novel drug development into ten months? The simple answer is, exactly.

C. Phase 3 Clinical Trials:
What about the large Phase 3 clinical trial reported by Polack, et al.?

This *report does not address the prevention* of Covid-19 in other populations, such as younger adolescents, children, and *pregnant women*. Safety and immune response data from this trial after immunization of adolescents 12 to 15 years of age will be reported subsequently, and *additional studies are planned to evaluate BNT162b2 in pregnant women*, children younger than 12 years, and those in special risk groups, such as immunocompromised persons.
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7745181/pdf/NEJMoa2034577.pdf, p. 12.]

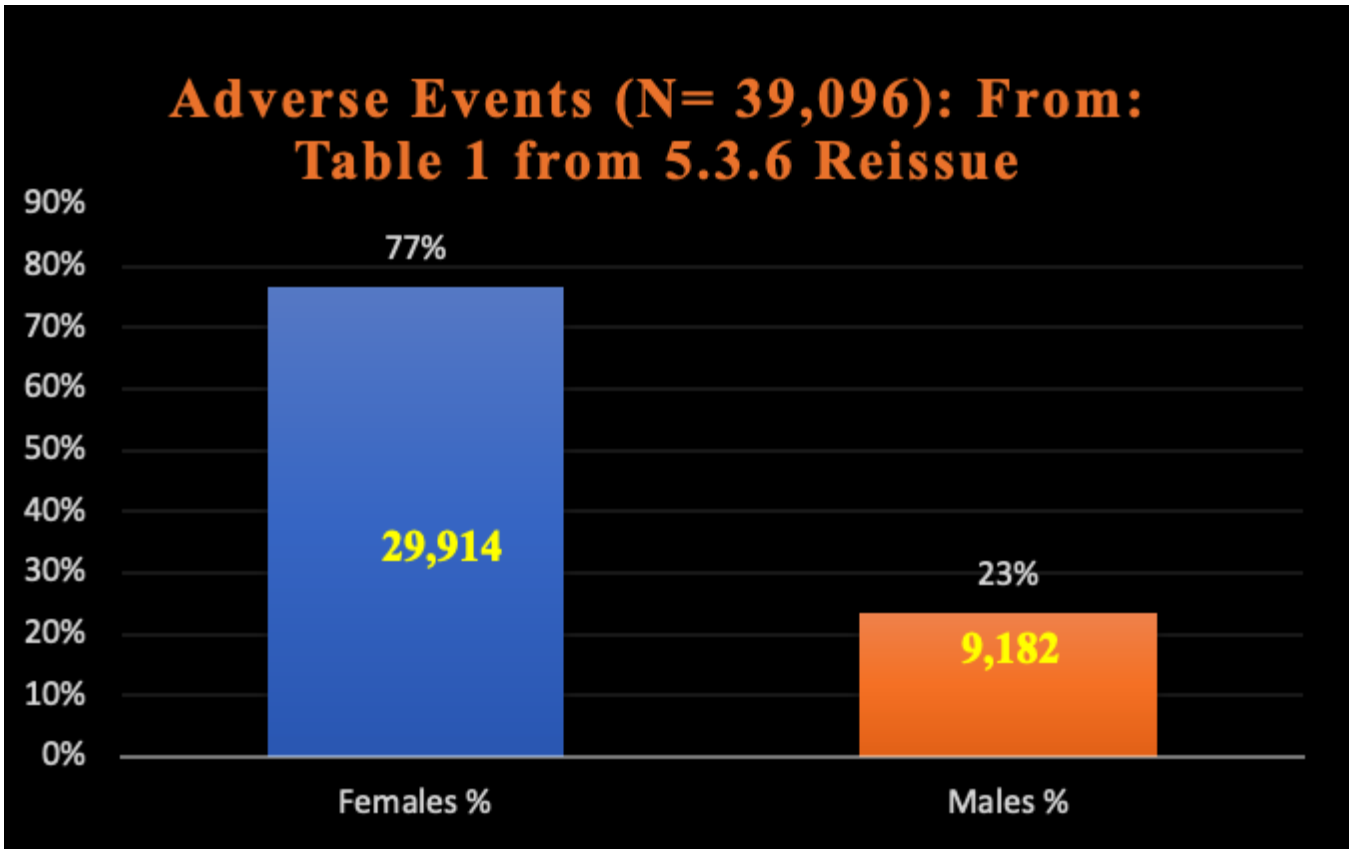
Keep in mind that this was published on December 16, 2020, mass inoculation began December 14, 2020, and by February 28, 2021, at least 35,691 pregnant women had been given LNP/mRNA gene therapy products and these pregnant women and their babies was largely lost to follow up.

This is another point about the Phase 3 trial subjects. Volunteers in the Placebo group were offered, and many were given, LNP/mRNA drugs *thus ending the randomized, controlled study that should have lasted at least two years*.
This was the best shot at understanding the possible harms of LNP/mRNA.

D. Sex Differences in Adverse Events and Adverse Events of Special Interest.

Another major omission from the CDC report about safety using LNP/mRNA in pregnant women concerns the data from Pfizer summary report 5.3.6 that shows a strong signal of increased harms from the RNA drugs to women in general, as seen below in Chart 5. [For source data, reference https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf.]

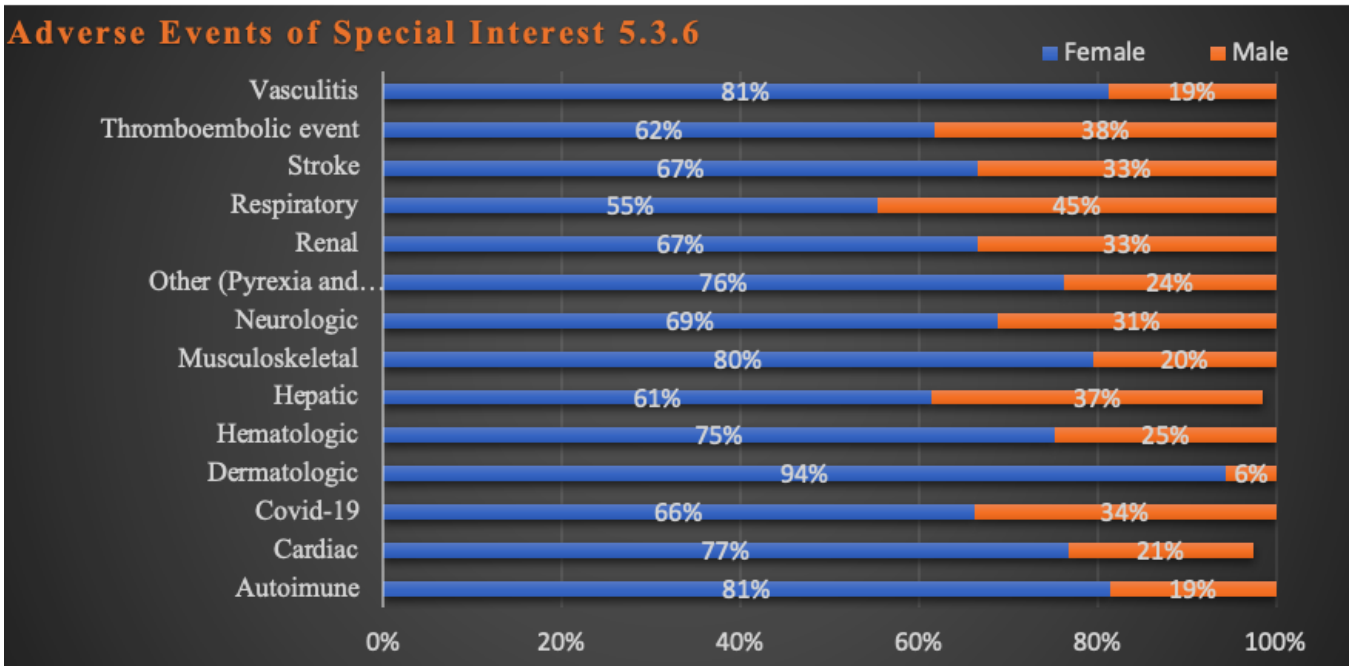
Chart 5: Sex Difference
Pfizer Adverse Events 5.3.6
2/28/2021



The chance this difference in reporting of adverse events between women and men is random is less than 0.001%.

The same findings apply to Adverse Events of Special Interest as shown in Chart 6 below.

Chart 6: AESI Sex Differences



These differences are also statistically significant at $p < 0.05$ in all but the following: Dermatologic, Hematologic, Renal, Vascular and "Other" categories by organ system.

A subsequent report confirmed the statistically significant differences in Reproductive System and Function AEs with strong predominance of harms to women's reproductive systems and functions compared with those of men. [https://dailyclout.io/women-have-three-times-the-risk-of-adverse-events-than-men-risk-to-the-reproductive-organs-is-even-greater-report/]

This data was collected during the same time interval as that covered by Shimabukuro, et al. and should have been known to the CDC and FDA doctors and scientists. This information was vital to provide proper informed consent to pregnant women specifically but applies to all women.

VI. Dr. Rubin, the *NEJM*, FDA and CDC

"But we're never gonna learn about how safe this vaccine is until we start giving it, that's just the way it goes. That's how we found out about-complications of other vaccines...And I do think that we should vote to approve it." said FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) panel member Dr. Eric Rubin, MD, at a hearing on October 26, 2021, during an all-day session to consider use of BNT162b2 in children aged 5-11.
[https://twitter.com/Techno_Fog/status/1453095851824459776 and
https://townhall.com/tipsheet/scottmorefield/2021/10/26/fda-panel-member-were-never-gonna-learn-about-how-safe-the-vaccine-is-until-we-start-giving-it-n2598]

It has been debated as to whether this remark was taken out of context or not, but, either way, it remains a remarkable statement in the whole context of widespread use of novel gene therapy products and is applicable to the subject of this paper.

Dr. Rubin is Editor-in-Chief of the *New England Journal of Medicine* (*NEJM*), a once prestigious medical journal, and Adjunct Professor of Immunology and Infectious Diseases at Harvard's T.H. Chan School of Public Health. Dr. Rubin is also a member of the FDA's VRBPAC.
"When politics and science meet, politics wins.". (Source unknown).
[https://www.psychologytoday.com/us/blog/darwins-subterranean-world/202105/politics-and-science-losing-combination]

During 2020, the NEJM published an article unrelated to the present work that used an obviously fraudulent data set that, because of complaints from the medical community, had to be retracted. In the context of this controversy Dr. Rubin wrote the following:

"Recently, substantive concerns have been raised about the quality of the information in that database. We have asked the authors to provide evidence that the data are reliable. In the interim and for the benefit of our readers, we are publishing this Expression of Concern about the reliability of their conclusions."

[See https://www.nejm.org/doi/full/10.1056/NEJMoa2007621 for an article published then retracted after numerous complaints about an obviously bogus data set. See for expression of concern: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7274164/pdf/NEJMc2021225.pdf. See retraction: https://www.nejm.org/doi/pdf/10.1056/NEJMe2020822?articleTools=true.]

It seems there was a precedent for faulty data sets in work published by the *New England Journal of Medicine*.

VII. Summary

The subject of this article was the safety determination by the CDC and FDA of LNP/mRNA experimental gene products in pregnant women.
The article fell short of any reasonable expectation of providing useful information concerning the risks to pregnant women and their babies. Accurate and reliable scientific data were not collected.
Shortcomings of the Shimabukuro, et al. report and the body of work it reports on are abundant. Here are 10 of them:

1. The Pre-Clinical evaluation of the effects of LNP/mRNA on pregnancy was inadequate.
2. Phase 1-3 Clinical Trials by Pfizer specifically excluded evaluation in pregnant women.
3. The control group from the Pfizer Phase 3 trial was compromised, ending perhaps the most direct and powerful tool to understand the long-term effects of these drugs well before the required two years had elapsed.
4. The Pfizer registry summarizing the first two and a half months of widespread use of LNP/mRNA identified the statistically significant warning signal of increased adverse events and adverse events of special interest after LNP/mRNA therapy in women, and this warning signal was not publicized.
5. The rates of spontaneous abortion, congenital anomalies, prematurity, and neonatal death were not determined with any degree of certainty.
6. 97% of the 35,691 pregnant women in the V-safe database and their babies who were injected with the experimental gene therapy drug had no outcomes recorded.
7. Candidates for LNP/mRNA products were not informed of AEs, AESIs, and dose-related harms associated with these products.
8. Absence of data from valid and reliable randomized controlled studies of pregnant women and their babies following treatment with LNP/mRNA products undermines a recommendation for these products in pregnant women.
9. Registry data is not appropriate for analysis of never-before-used gene therapy products.
10. The scientific integrity of this work was further compromised by multiple retrospective revisions of this work as revealed in the online publications June 17, 2021, September 8, 2021, and October 14, 2021.

[https://www.nejm.org/doi/full/10.1056/NEJMx210016,
https://www.nejm.org/doi/full/10.1056/NEJMc2113891,
https://www.nejm.org/doi/full/10.1056/NEJMc2113516,
https://www.nejm.org/doi/full/10.1056/NEJMx210017j, and
https://www.nejm.org/doi/full/10.1056/NEJMe2107070.]

Conclusion:

An IMMEDIATE cessation of the use of mRNA/LNP vaccines in pregnant women is mandatory until further research proves beyond doubt that they are safe to give to pregnant women.
It is necessary now to submit Freedom of Information Act (FOIA) requests for the notes of the peer reviewers, the editorial staff of the *New England Journal of Medicine*, and the FDA and CDC officials who raised no alarms when they saw that the vast majority of pregnant women in the CDC's 'V-Safe' study – one that was invoked extensively as justification to inject millions of pregnant women with mRNA injections – were simply lost.

Report 37: "2021 CDC and FDA Misinformation – Retroactive Editing, Erroneous Spontaneous Abortion Rate Calculation, Obfuscation in the *New England Journal of Medicine*" by Robert W. Chandler, MD, MBA – Team 5.

The following article is a follow-up to Dr. Chandler's report, "Data Do Not Support Safety of mRNA COVID Vaccination for Pregnant Women," [https://dailyclout.io/data-do-not-support-safety-of-mrna-covid-vaccination-for-pregnant-women/] which reviewed "Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons," New England Journal of Medicine, April 21, 2021, and June 17, 2021. ***To best understand this report, please read the previous report first.***

Fortitude is required for anyone who endeavors to try to understand the surveillance and reporting of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) concerning safety of Pfizer and Moderna's LNP/mRNA gene therapy products in pregnant women in the year following widespread distribution of these products (December 14, 2020, until December 14, 2021) as reported in the *New England Journal of Medicine (NEJM)*, *Research Square*, *Obstetrical and Gynecological Survey* and *Obstetric Anesthesia Digest* during calendar year 2021. [Shimabukuro, et al, *NEJM*, April 21, 2021/October 14, 2021; DOI: 10.1056/NEJMoa2104983, https://www.nejm.org/doi/full/10.1056/NEJMoa2104983. https://www.nejm.org/doi/full/10.1056/NEJMe2107070. https://www.nejm.org/doi/full/10.1056/NEJMc2113516. https://www.researchsquare.com/article/rs-798175/v1. https://journals.lww.com/obgynsurvey/Abstract/2021/12000/Preliminary_Findings_of_mRNA_COVID_19_Vaccine.7.aspx. https://journals.lww.com/obstetricanesthesia/Abstract/2021/12000/Preliminary_Findings_of_mRNA_Covid_19_Vaccine.2.aspx.]

The CDC used two voluntary registries to track pregnant women after they were injected with at least one dose of LNP/mRNA genetic therapy drugs, the V-safe/Pregnancy Registry that was created for Covid-19 specifically and the long-standing Vaccine Adverse Event Reporting System (VAERS) that has tracked adverse events following administration of vaccines since 1990. [https://www.cdc.gov/vaccinesafety/pdf/vsafe-pregnancy-surveillance-protocol-508.pdf. https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf. https://vaers.hhs.gov/.]

Advice to self: Be prepared to download and save documents before they are changed online. Make liberal use of screenshots for important discoveries, as information in the digital age can be very fluid, unlike the memory hole of Orwell which required mechanical incineration of unfavorable information in hard copy form and continuous issuance of updated versions of the past. We now have a digital version of the memory hole.

Registry Data

The protocol for V-safe is currently in a 69-page Version 4 from March 10, 2022, entitled "V-safe Active Surveillance for Covid-19 Vaccine Safety and Amendment." [https://www.cdc.gov/vaccinesafety/pdf/vsafe-pregnancy-surveillance-protocol-508.pdf and https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf] Perhaps you will be able to find Version 1, but it will be more productive to move on to the first published results from these databases by Shimabukuro, et al. in the April 21, 2021, issue of *NEJM*. [Shimabukuro, et al, NEJM, April 21, 2021/October 14, 2021; DOI: 10.1056/NEJMoa2104983, https://www.nejm.org/doi/full/10.1056/NEJMoa2104983.]

Following publication, Shimabukuro's article had a very confusing history. A spreadsheet tracking the changes in publications by authors from the CDC and FDA reporting on data queries from the CDCs V-safe/Pregnancy Registry and VAERS 12/14/2020 through 2/28/2021 is attached as **Exhibit I**.

In brief, the publication history of the "Preliminary Findings…" article and its progeny in the year following the late 2020 Emergency Use Authorization (EUA) is as follows:

1. April 21, 2021, *NEJM*: Shimabukuro, et al. Original Article published. [Shimabukuro, et al, *NEJM*, April 21, 2021/October 14, 2021; DOI: 10.1056/NEJMoa2104983, https://www.nejm.org/doi/full/10.1056/NEJMoa2104983.]
2. June 17, 2021, *NEJM* recycled "Original Article" from April 21, 2021, published. [Shimabukuro, et al, *NEJM*, April 21, 2021/October 14, 2021; DOI: 10.1056/NEJMoa2104983, https://www.nejm.org/doi/full/10.1056/NEJMoa2104983.]
3. Reportedly, the June 17, 2021, republished "Original Article" was modified retroactively on September 8, 2021, changing the "original" text online. [https://www.nejm.org/doi/full/10.1056/NEJMx210016]
4. Zauche, et al. made a confusing second attempt to put forth a number for the rate of spontaneous abortions in the August 9, 2021, issue of *Research Square.* [https://www.researchsquare.com/article/rs-798175/v1] This material was republished in the October 14, 2021, NEJM with the bulk of the paper appearing in the form of a Supplement. [https://www.nejm.org/doi/full/10.1056/NEJMc2113891]
5. The September 9, 2021, edits of the June 17, 2021, Shimabukuro, et al. paper were reported in authorless "Corrections" in the October 14, 2021, issue of *NEJM*. The June 17, 2021, online version was modified retroactively. [https://www.nejm.org/doi/full/10.1056/NEJMe2107070]
6. The abstract from the edited June 17, 2021, version of the *NEJM* article was published in the December issue of Obstetrical and Gynecological Survey. [https://journals.lww.com/obgynsurvey/Abstract/2021/12000/Preliminary_Findings_of_mRNA_COVID_19_Vaccine.7.aspx] The study by Zauche, et al. was not mentioned. [https://www.researchsquare.com/article/rs-798175/v1]

7. The full form of the September 8, 2021, edited June 17, 2021, republication of the April 21, 2021, original was republished in the December issue of *Obstetrical Anesthesia Digest*. [https://journals.lww.com/obstetricanesthesia/Abstract/2021/12000/Preliminary_Findings_of_mRNA_Covid_19_Vaccine.2.aspx] The analysis by Zauche, et al. was not mentioned.
8. As of September 2022, the April 21, 2021, *NEJM* publication was no longer available online.
9. As of September 2022, the September 8, 2021, *NEJM* corrections were no longer available online.

In Zauche, et al. CDC and FDA authors were joined by colleagues from the United States Department of Energy, United States Public Health Service, National Institute of Environmental Health Sciences, and the Department of Mathematics at the University of California - San Diego in the special analysis of Zauche, et al. [https://www.nejm.org/doi/full/10.1056/NEJMc2113891]

No Updates in 2021 as Pregnancies Complete

By December 2021, all 3,958 pregnant women entered into the V-safe Pregnancy Registry would have completed their pregnancies yet, other than Zauche, et al., no new data was added to the various reports from April through December 2021. [https://www.researchsquare.com/article/rs-798175/v1 and https://journals.lww.com/obgynsurvey/Abstract/2021/12000/Preliminary_Findings_of_mRNA_COVID_19_Vaccine.7.aspx] Even after Zauche, et al. was published in August and republished in October, the December versions of Shimabukuro, et al. report on the same data set reported in April 2021.

[Shimabukuro, et al, *NEJM*, April 21, 2021/October 14, 2021; DOI: 10.1056/NEJMoa2104983, https://www.nejm.org/doi/full/10.1056/NEJMoa2104983. https://journals.lww.com/obgynsurvey/Abstract/2021/12000/Preliminary_Findings_of_mRNA_COVID_19_Vaccine.7.aspx. https://journals.lww.com/obstetricanesthesia/Abstract/2021/12000/Preliminary_Findings_of_mRNA_Covid_19_Vaccine.2.aspx.]

Shimabukuro, et al. and Edits

Shimabukuro, et al. reported "Preliminary Findings of mRNA Covid-19 Safety in Pregnant Persons," April 21, 2021, in the *New England Journal of Medicine*. [Shimabukuro, et al, *NEJM*, April 21, 2021/October 14, 2021; DOI: 10.1056/NEJMoa2104983, https://www.nejm.org/doi/full/10.1056/NEJMoa2104983.] One may be able to find this in a library but search online and you are likely to find only the June 17, 2021, version that was retrospectively edited on September 8, 2021, changing the June 17, 2021, version of the April 21, 2021, original. The actual September edit notification has not yet been located online, but the edit was documented later in the October 14, 2021, issue of *NEJM*. [https://www.nejm.org/doi/10.1056/NEJMx210016] The edits and versions of Shimabukuro, et al. are detailed in **Exhibit II.**

Riley and Edits

In the same June 17, 2021, issue that had the Shimabukuro, et al. republication there was an editorial by Dr. Laura Riley, MD, Chairman of the Department of Obstetrics and Gynecology at Weill Cornell Medical School. [https://www.nejm.org/doi/full/10.1056/NEJMe2107070 and https://directory.weill.cornell.edu/person/profile/lar9110] **Exhibit III**.

Dr. Riley is also a member of the *New England Journal of Medicine Editorial Board* (**Exhibit III**) In her editorial, Dr. Riley stated:

"... clinicians relied on developmental and reproductive animal data from Moderna that showed no safety concerns, and *there was no biologically plausible reason that the mRNA technology would be harmful in pregnancy*."
[https://www.nejm.org/doi/pdf/10.1056/NEJMe2107070?articleTools=true, p. 2342.]

This statement is simply not consistent with the fact that the LNP/mRNA products were not thoroughly evaluated in pre-clinical studies and received no formal testing by Pfizer in pregnant women as noted in the Polack, et al report of Phase 3 clinical trials.
[https://www.nejm.org/doi/full/10.1056/NEJMoa2034577 and https://robertchandler.substack.com/p/pfizer-pre-clinical-studies-review]
Dr. Riley went on to note that Shimabukuro, et al. reported spontaneous abortion in 12.6% of the 827 registry participants who had completed pregnancies, a figure obtained by dividing 104 spontaneous abortions in the first 20 weeks by the 827 completed pregnancies.

The problem with this calculation is that 700 of the 827 pregnancies followed to completion were given the LNP/mRNA product in their third trimester and should not have been included in the denominator. The various calculations that have been attempted with these data were presented in an earlier article. [https://dailyclout.io/data-do-not-support-safety-of-mrna-covid-vaccination-for-pregnant-women/]
This error was addressed in a stealth edit in a September 8, 2021, *NEJM* message that was fully reported in the October 14, 2021, issue of *NEJM* as noted in **Exhibit III**. Other edits were also made, as noted in **Exhibit III**.
[https://www.nejm.org/doi/full/10.1056/NEJMx210017?query=recirc_curatedRelated_article]

Sun Correspondence

Dr. Hong Sun, PhD of Antwerp, Belgium questioned the calculation of 12.6% spontaneous abortion rate, pointing out that the denominator included 700 pregnant women who received their first dose in the trimester and should not have been included in a calculation of spontaneous abortion rate. **Exhibit IV**. [https://www.nejm.org/doi/full/10.1056/NEJMc2113516]

It is not clear when Dr. Sun's letter was received, but this note is in the October 14, 2021, publication of his "Correspondence":

"This letter was published on September 8, 2021, at NEJM.org."
[https://www.nejm.org/doi/full/10.1056/NEJMc2113516]

However, there is a citation in Dr. Sun's correspondence that references the Shimabukuro, et al. paper in a Letter to the Editor of *American Journal of Obstetrics and Gynecology* published August 3, 2021:

"Finally, I consider that such an adjustment to EPL risk calculation is not limited to the calculation of the risk for pregnant women with COVID-19. In addition, it should be applied when calculating the EPL to evaluate the impact of COVID-19 vaccination where the period between pregnancy and vaccination is unintentionally excluded." [Shimabukuro, et al, *NEJM*, April 21, 2021/October 14, 2021; DOI: 10.1056/NEJMoa2104983, https://www.nejm.org/doi/full/10.1056/NEJMoa2104983.]

Perhaps Sun's criticism prompted the September 8, 2021, edit of the June 17, 2021, version of Shimabukuro, et al. and the authorless edit of the Riley editorial in the same issue?

The CDC's Dana M. Meaney-Delman, MD, Sascha R. Ellington, PhD and Tom T. Shimabukuro, MD agreed with Dr. Sun:

"We agree that the denominator used in that proportion — 827 completed pregnancies — is not an appropriate denominator for the calculation of a risk estimate or rate.
[https://www.nejm.org/doi/full/10.1056/NEJMc2113516]

In this preliminary report, follow-up information was missing for the majority of pregnancies in which exposure to vaccination occurred in early pregnancy."
[https://www.nejm.org/doi/full/10.1056/NEJMc2113516]

They had a 20-week gestational history on only 204 of 1,224 pregnant women receiving at least one injection "before conception" or "in the first trimester." Before conception? How much before conception? When exactly were these women injected?

They go on to say that of these 1,224 women, they had data only on 204 women through 20 weeks. What do these 204 women with 20 weeks of follow-up have to do with the 104 with spontaneous abortions? Different data queries perhaps?

In the last paragraph of their response to Dr. Sun's letter, they mentioned completing a telephone survey of the "905 other pregnancies," and they "enrolled additional persons in the V-safe pregnancy registry." More added? How many? Of what kind of cases?

Not done yet, they cite the Zauche, et al. "Correspondence" of which Meany-Delman, et al. is a co-author in the same issue of the *Journal*. In the "Correspondence," they fail to reference their August

9, 2021, Zauche, et al. preprint paper in *Research Square*, but they attach a 15-page supplement containing the *Research Survey* data set and analysis. The third publication, again without peer review, of Zauche, et al. appeared in the October 14, 2021, *NEJM* along with Meany-Delman, et al. reporting about the same Zauche, et al. August 2021 original report.
[https://www.nejm.org/doi/full/10.1056/NEJMc2113891]

Suddenly, one begins to empathize with the World War II bomber crews flying through heavy Triple A. Stealth edits are now joined with stealth publications.

More Zauche, et al.
[https://www.researchsquare.com/article/rs-798175/v1]

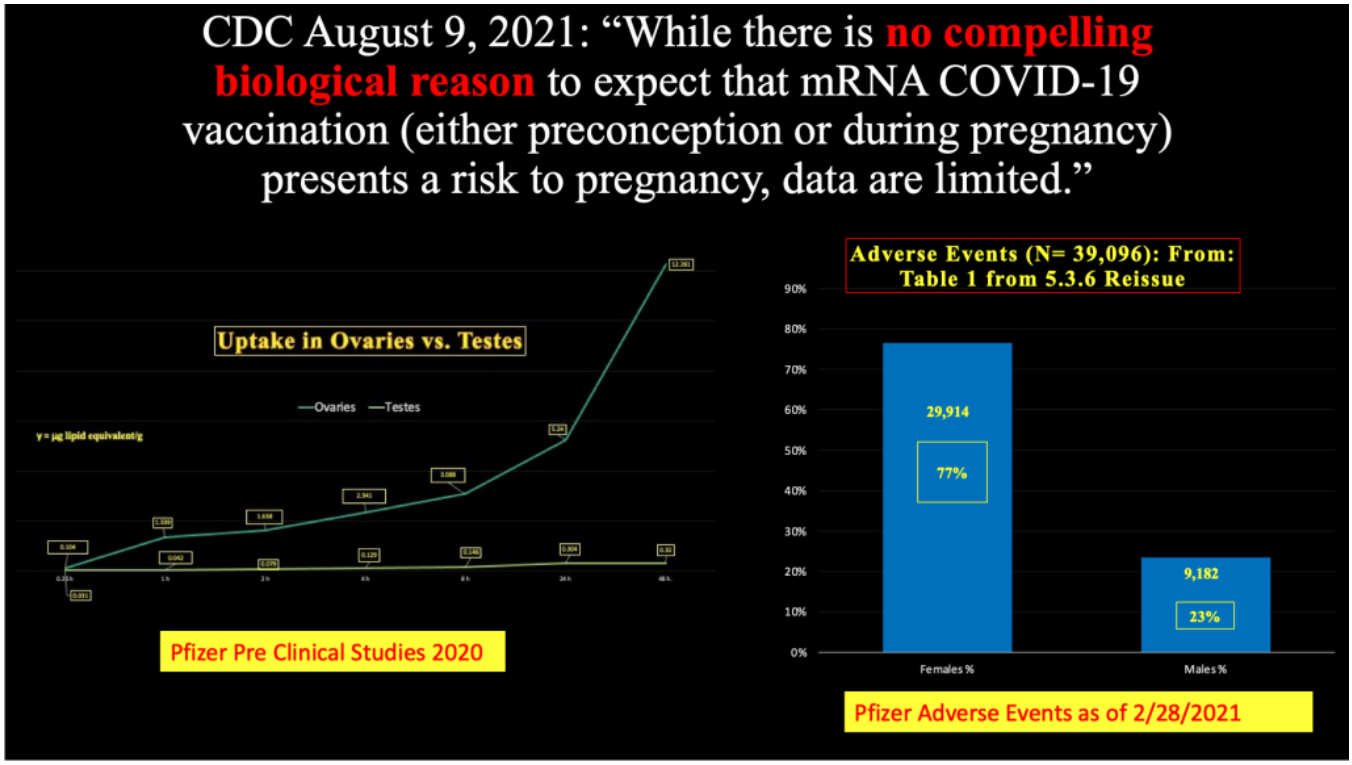
Exhibit V presents a summary of the Zauche, et al. paper.
In the August 2021 version of this presentation of data, the authors make a statement similar to that of Dr. Riley – that they knew of no compelling biologic reason why these novel, never-before-used concoctions of two cationic lipids, ALC-0159, ALC-0315, novel messenger ribonucleic acid and other disclosed and undisclosed substances would have a negative impact on pregnant females and their babies.

At the time of this August 2021 declaration, the CDC and FDA had to be aware of the ovarian uptake of LNP/mRNA revealed in Pfizer document "2.4 Nonclinical Overview" [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf] reporting on pre-clinical studies in Wistar-Han rats in 2020 and the harms to women that had surfaced as of February 28, 2021.
[https://robertchandler.substack.com/p/pfizer-pre-clinical-studies-review, https://robertchandler.substack.com/p/pfizer-document-536-cumulative-analysis, and https://dailyclout.io/women-have-three-times-the-risk-of-adverse-events-than-men-risk-to-the-reproductive-organs-is-even-greater-report/]

Chart 1 presents ovarian uptake of LNP/mRNA in preclinical studies and disproportionate harmful effects of LMP/mRNA in women as of March and April 2021.

Chart 1:

Ovarian uptake of LNP/mRNA from 2020 Pre-Clinical Studies Pfizer Confidential Document 2.4 (left) and Female Predominance in Adverse Events and Adverse Events of Special Interest (right) gathered by Pfizer and reported in Pfizer Confidential Document 5.3.6. [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf and https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf]



A member of the European Medicines Agency (EMA), however, had expressed concern about the lipid component of these products on December 22, 2021:

"According to the product information supplied by the European Medicines Agency, two of the main components of Pfizer's Comirnaty vaccine are ALC-0315 and ALC-0159. Echelon, the manufacturer of these nanoparticles, specifies that they are 'for research only and not for human use'. Administering a vaccine – particularly to children – which contains unauthorised (sic) excipients is illegal, dangerous and unethical.

1. How does the Commission justify distributing a product that is harmful to public health and, as such, infringes Article 168(1) of the Treaty on the Functioning of the European Union?
2. How can it explain such a serious oversight – particularly given that the EU founded a European Health Emergency Preparedness and Response Authority (HERA) in September 2021 – and how will it avoid similar occurrences in future?

3. What does it intend to do to put an end to the persistent threat that unauthorised (sic) vaccine components pose to people in Europe?" [https://www.europarl.europa.eu/doceo/document/P-9-2021-005690_EN.html]

During the time from December 14, 2020, until sometime in Spring of 2022, Pfizer had received tens of thousands of Adverse Event (AE) reports concerned with reproductive organ and reproductive function in women. [https://dailyclout.io/women-have-three-times-the-risk-of-adverse-events-than-men-risk-to-the-reproductive-organs-is-even-greater-report/]

Table 1 gives a partial listing of diagnoses and number of reports by diagnostic category. To be fair, this list was published in April 2022. However, this list had been growing steadily all through the first year of widespread distribution and transfection of uncounted millions of pregnant women with LNP/mRNA products.

Table 1

"APPENDIX 2.1 Cumulative Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class," April 16, 2022 [https://www.tga.gov.au/sites/default/files/2022-08/foi-3727-01.pdf]

Total AEs N =	**923194**
Heavy menstrual bleeding	27685
Menstrual disorder	22145
Menstruation irregular	15083
Menstruation delayed	13989
Dysmenorrhea	13904
Intermenstrual bleeding	12424
Amenorrhea	11363
Polymenorrhea	9546
Breast pain	4800
Vaginal hemorrhage	4699
Oligomenorrhea	3437
Hypomenorrhea	2643
Postmenopausal hemorrhage	2456
Abortion spontaneous	1809
Breast swelling	1339
Menstrual discomfort	1199

Premenstrual syndrome	998
Breast tenderness	792
Menometrorrhagia	632
Adnexa uteri pain	609
Premenstrual pain	585
Breast enlargement	483
Vaginal discharge	480
Breast discomfort	443
Mastitis	392
Ovulation pain	347
Endometriosis	337
Menstrual cycle management	308
Anovulatory cycle	273
Uterine pain	270
Abnormal withdrawal bleeding	265
Uterine hemorrhage	231
Vulvovaginal pain	191
Ovulation delayed	181
Premature baby	181
Vulvovaginal mycotic infection	173
Breast cancer	147
Fetal death	147
Fetal growth restriction	124
Vulvovaginal candidiasis	122
Breast cyst	115
Genital hemorrhage	115
Breast edema	113
Abnormal uterine bleeding	100
Pelvic venous thrombosis	98
Labor pain	95
Uterine leiomyoma	91
Polycystic ovaries	82
Breast discharge	71
Vulvovaginal pruritis	71
Breast disorder	68

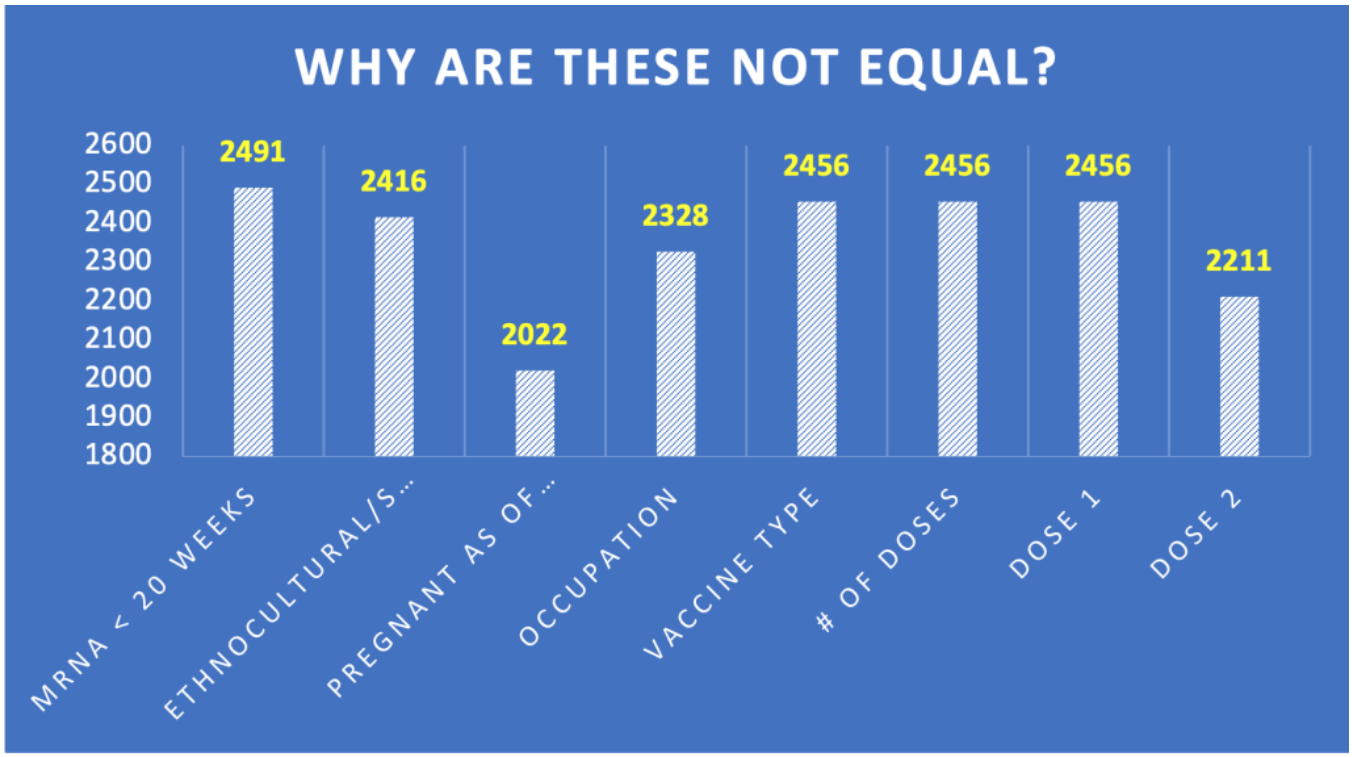
Uterine contracture during pregnancy	68
Ectopic pregnancy	67
Premature labor	64
Morning sickness	62
Vaginal infection	60
Vulvovaginal discomfort	59
Abortion	58
Premature menopause	58
Vulval ulceration	56
Stillbirth	56
Vulvovaginal dryness	54
Coital bleeding	46
Ovarian cyst rupture	44
Premature delivery	44
Endometrial thickening	42
Genital burning syndrome	42
Adenomyosis	41
Breast abscess	41
Fetal heart rate abnormal	41
Menarche	40
Premenstrual headache	40
Uterine contractions abnormal	40
Breast induration	39
Premature rupture of membranes	37
Uterine polyp	37
Vulvovaginal swelling	37
Abortion induced	36
Uterine inflammation	36
Vulval hemorrhage	34
Pelvic inflammatory disease	33
Pregnancy	32
Pelvic discomfort	30
Premature menarche	27
Premature ovulation	27
Breast hematoma	26

Infertility female	26
Postpartum hemorrhage	26
Uterine disorder	26
Pelvic hemorrhage	25
Noninfective oophoritis	23
Vaginal ulceration	23
Dyspareunia	22
Ovarian disorder	22
Unintended pregnancy	22
Vaginal order	22
Vulvovaginal inflammation	21
Breast cancer	20
Breast disorder female	20
Hemorrhagic ovarian cyst	20
Placental disorder	20
Gestational diabetes	19
Abortion early	19
Endometrial disorder	18
Nipple inflammation	18
Endometrial hyperplasia	18
Ovarian hemorrhage	17
Ovarian failure	16
Vulvovaginal erythema	16
Ovarian vein thrombosis	15
Polymenorrhagia	15
Threatened labor	14
Fibrocystic breast disease	13
Ovarian enlargement	13
Uterine enlargement	13
Cervix hemorrhage uterine	12
Breast atrophy	11
Breast hemorrhage	11
Breast neoplasm	11
Caesarean section	11
Cervical dysplasia	11
Pelvic girdle pain	11

Vaginal disorder	11
Vulval disorder	11
Bartholin's cyst	10
Decidual cyst	10
Fetal cardiac disorder	10
Fetal growth abnormality	10
Fetal vascular malperfusion	10
Vaginal cyst	10
Small for dates baby	10
Vaginal cyst	10

Criticisms of Zauche, et al.

1. **Nonrandom sample.**



The data set reported by Zauche, et al. was far from a random and representative sample of pregnant women. In fact, 80 percent were white (1,923/2,416) and 94 percent were healthcare workers. Mukherjee, et al. examined the miscarriage rate in whites versus black and found:

> "Our primary finding was that black women have a nearly 2-fold higher risk of miscarriage compared with white women during gestational weeks 10–20, while there was no apparent

difference in the risk of earlier miscarriage."
[https://academic.oup.com/aje/article/177/11/1271/97504]

Another curious feature of this sample is that each category has a different number of subjects. We need to know how this happened. Were each of these categories a separate database query?

2. **Only 1073 or 49% of pregnant women received two doses during preconception or first trimester.**

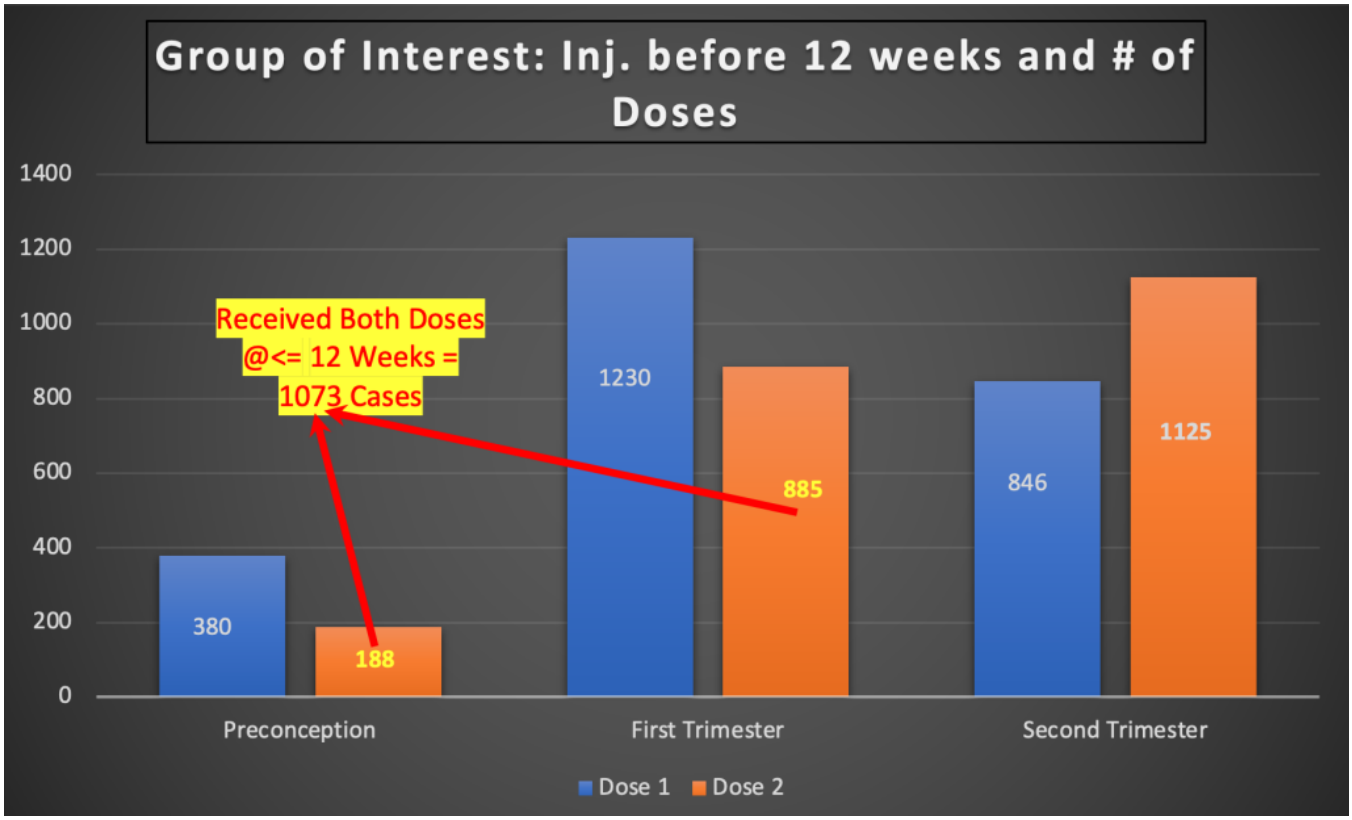
This group has no associated data for spontaneous abortions. Demographics, comorbidities and number of spontaneous abortions for this group were not provided. In the August 9, 2021, version of Zauche, et al. in *Research Survey*, readers were allowed to comment. Robert Clark made the following comment:

Robert Clark Comment on article
on 20 Aug, 2021

"A key flaw in the study is it looked at the average number of SAB's after at least one dose. **It is well-known the 2nd dose is the more injurious one, in terms of side effects.** By including also those who had only one dose, you decrease the size of the effect."
[https://www.researchsquare.com/article/rs-798175/v1]

Mr. Clark was on point as the Zauche, et al. data shown in Chart 2 reveals.

Chart 2: The Most Important Study Group



Outcome of pregnancy for these 1,073 women should have been reported as the single most meaningful subgroup. It was not done.

3. **Omission of first six weeks data.**

Zauche, et al. excluded subjects who miscarried during the first six gestational weeks:
"The inclusion of participants pregnant at 6 completed weeks' gestation reflects when pregnancies are generally recognized and is consistent with previous literature estimating SAB in the general population.[5, 8–10, 15]"

This remarkable quote misstates the literature. For example, Goldhaber and Fireman found that the more sensitive the testing, the more the frequency of miscarriage in the first six weeks rises.

a. "The fetal life table revisited: spontaneous abortion rates in three Kaiser Permanente cohorts":
"The major difference in survival between the three Kaiser Permanente cohorts was in the earliest gestational week of observation, week 5 from the last menstrual period, where the older data were sparse and potentially biased. High loss rates during this week accounted for one-fourth to one-third of the cumulative risk observed in the older studies."

"Because of improved reliability of early pregnancy testing and an emphasis on early prenatal care, the mean gestational age at entry to the 1981-1982 cohort was 10.4 weeks from the last menstrual period compared to 14.3 weeks and 13.7 weeks for the older studies. All three studies showed a peak for risk of spontaneous abortion around weeks 10-12 from the last menstrual period."

[Goldhaber, M. K., & Fireman, B. H. (1991). The fetal life table revisited: spontaneous abortion rates in three Kaiser Permanente cohorts. *Epidemiology (Cambridge, Mass.)*, *2*(1), 33–39. https://pubmed.ncbi.nlm.nih.gov/2021664/]

This finding reinforces a conclusion reported in an earlier study by Wilcox, et al. in which they found that the more carefully they looked for spontaneous abortion in the first six weeks the more miscarriages they identified.

b. "Incidence of Early Loss of Pregnancy"

- Allen J. Wilcox, M.D., Ph.D.,
- Clarice R. Weinberg, Ph.D.,
- John F. O'Connor, Ph.D.,
- Donna D. Baird, Ph.D.,
- John P. Schlatterer, M.S.,
- Robert E. Canfield, M.D.,
- Glenn Armstrong, Ph.D.,
- and Bruce C. Nisula, M.D.

"*We identified 198 pregnancies by an increase in the hCG level near the expected time of implantation. Of these, 22 percent ended before pregnancy was detected clinically. Most of these early pregnancy losses would not have been detectable by the less sensitive assays for hCG used in earlier studies.*
The total rate of pregnancy loss after implantation, including clinically recognized spontaneous abortions, was 31 percent. Most of the 40 women with unrecognized early pregnancy losses had normal fertility, since 95 percent of them subsequently became clinically pregnant within two years."
[Wilcox, A. J., Weinberg, C. R., O'Connor, J. F., Baird, D. D., Schlatterer, J. P., Canfield, R. E., Armstrong, E. G., & Nisula, B. C. (1988). Incidence of early loss of pregnancy. *The New England Journal of Medicine*, *319*(4), 189–194. https://pubmed.ncbi.nlm.nih.gov/3393170/]

With the first-time use of a novel, genetically active drug never tested in pregnant women, the best science should have been employed to look particularly closely at spontaneous abortion in the first six weeks. The same is true for preterm births, congenital deformities, complicated deliveries, placental anomalies, and neonatal death. *This was simply not done.*

4. **Missing data.**

Zauche, et al. report:
"Enrolled participants receive a telephone follow-up each trimester, during the postpartum period, and three months following live births."
However, two of the 19 comments entered in the "Comments" section by readers of the August 2021 *Research Square* preprint wrote about having had no follow-up after enrolling in the V-safe Pregnancy Registry:

Dani K on 20 Aug, 2021
"I was a part of the v safe registry. I received the vaccine 32 days prior to becoming pregnant. I reported my pregnancy to the v safe registry 3 times, and was told someone would contact me each time. No one ever did. I subsequently miscarried at 10 weeks. My miscarriage was not counted in this study. Who else's miscarriage or adverse pregnancy outcome was left out? While I do not personally believe the vaccine caused my miscarriage, one has to wonder about the accuracy of this data."

Shaena Kauffman on 15 Aug, 2021
"I find this study confusing. I registered in the v-safe program and never got one phone call, only text update requests. I repeated a spontaneous miscarriage which occurred in my 2nd trimester, 2 weeks after my 2nd Covid dose. I reported this. No one contacted me. This data shows only 11 SAB. I highly doubt it is counting me. Again, I reported all the ways you can. I got my VARES [sic] ID. Not one call. Is it counting events reported in the database? If you search you will see far more than 11 reports. Additional clarification on the data is needed."
[https://www.researchsquare.com/article/rs-798175/v1]

Perhaps this is how you capture the data for a tiny nonrepresentative sample of the hundreds of thousands of pregnant women who were transfected with LNP/mRNA gene therapy products?

5. **Data is not stratified.**

A proper study of the complex subject of adverse effects on the human reproductive cycle should include stratification in adequately powered samples. What drug was administered, what were the batch numbers, dates of administration relative to gestation, age, comorbidities and relevant demographic diversity are important. The V-safe Pregnancy Registry contained little of this data.

6. **Sample size is small.**

Only 1,073 preconception or first trimester pregnant women were given both doses. Demographics, spontaneous abortion numbers, and outcomes are missing for this critical group.
By this point in time, millions of pregnant women had been given LNP/mRNA products. A very small, nonrandom sample is likely to provide only incorrect and or unusable data.

7. **Pregnancy outcome data not provided.**

Zauche, et al. did not have outcome data on the cases they presented.

Shimabukuro, et al., December 2021 Versions
[https://journals.lww.com/obgynsurvey/Abstract/2021/12000/Preliminary_Findings_of_mRNA_COVID_19_Vaccine.7.aspx and
https://journals.lww.com/obstetricanesthesia/Abstract/2021/12000/Preliminary_Findings_of_mRNA_Covid_19_Vaccine.2.aspx]

The 12 months following widespread injection of LNP/mRNA gene therapy products in pregnant women saw a reiteration of the calculation of *Total Fetal Loss* figure of 13.6% or 115/827 in two final publications by the government health agencies. Both publications were in the Ob Gyn literature, **Exhibit VI**.
[https://journals.lww.com/obgynsurvey/Abstract/2021/12000/Preliminary_Findings_of_mRNA_COVID_19_Vaccine.7.aspx and
https://journals.lww.com/obstetricanesthesia/Abstract/2021/12000/Preliminary_Findings_of_mRNA_Covid_19_Vaccine.2.aspx]

The year ended much as it had begun, except for the correction of *Table 4 in the original April 21, 2021, original version of Shimabukuro, et al.*
No denominator exists *to calculate the rate of spontaneous abortion in pregnant women injected with LNP/mRNA experimental genetic material.* **Exhibit VII**.

Further Studies 2021-2022: Clinical Trials Notation
[https://clinicaltrials.gov/ct2/show/NCT04754594?term=BNT162b2&draw=2&rank=10]

On July 15, 2022, there was a notice on ClinicalTrials.gov concerning completion of a randomized, placebo-controlled, observer-blind study of safety, tolerability, and immunogenicity of two doses, 21 days apart, in third trimester pregnant women. **Exhibit VIII.**

To date no results have been released from this study.

"However, only women in the third trimester were recruited for this study." Unfortunately, it is the first trimester about which it is vital to have data. Why does a study of pregnant women given BNT162b2 during gestational weeks 27-34?

Obfuscation

The essence of the CDC/FDA reporting in the first 12 months follow-up of 35,691 pregnant women entered into the V-safe database boils down to known outcomes in 827. This could have been summarized in the final version of Table 4 in the June 17, 2021, version of Shimabukuro, et al. [https://www.researchsquare.com/article/rs-798175/v1] Tables 1-3 and Chart 1 are presented in **Exhibit IX** for reference.

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	*no./total no. (%)*
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk[15-17]‡	Not applicable	104
Stillbirth: ≥ 20 wk[18-20]	<1	1/725 (0.1)§
Neonatal outcome among live-born infants		
Preterm birth: <37 wk[21,22]	8–15	60/636 (9.4)¶
Small size for gestational age[23,24]‖	3.5	23/724 (3.2)
Congenital anomalies[25]**	3	16/724 (2.2)
Neonatal death[26]††	<1	0/724

There is little of value in the rest of the Shimabukuro et al. paper in its various versions, as well as its progeny; but the reader must fight through a sizable smokescreen of various data sets with no outcome. We will examine this smokescreen in some detail.

Spontaneous abortion:

The double sword footnote in the table above informs the reader that there is no suitable denominator for the 104 spontaneous abortions, so a rate of abortion cannot be determined.

‡ A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation. No denominator was available to calculate a risk estimate for spontaneous abortions, because at the time of this report, follow-up through 20 weeks was not yet available for 905 of the 1224 participants vaccinated within 30 days before the first day of the last menstrual period or in the first trimester. Furthermore, any risk estimate would need to account for gestational week–specific risk of spontaneous abortion.

Stillbirth:
A stillbirth was reported to have occurred in 1 of 725 or 0.1% of some unknown "group." However, the gestational age at the time of injection was not spelled out. To be meaningful, this data needs to be stratified by trimester, Moderna versus Pfizer, mothers' ages, prior gestational history, comorbidities. We do know that only 127 mothers were injected in the first or second trimester and were followed to completion. Here is the footnote for stillbirths:

§ The denominator includes live-born infants and stillbirths.

Preterm birth:
Preterm births occurred 60 of 636 pregnancies. The origin of this denominator of 636 is not provided. The footnote for this entry is not much help in revealing the origin of the 636 figure, but we do learn that all three trimesters were included. As in the case of stillbirth, many relevant parameters are absent.

¶ The denominator includes only participants vaccinated before 37 weeks of gestation.

Small size for gestational age:

The denominator here is 724 or the same as for stillbirth minus the stillbirth. This pattern is repeated for congenital anomalies and neonatal death.

The matter to debate here is whether any of these numbers are valid and reliable estimates of rates of spontaneous abortion, stillbirth, preterm birth, congenital anomalies, and neonatal death as none of the denominators are reliable indicators of what happened to a representative large sample of mothers injected with LNP/mRNA products during their first term.

What is provided in Tables 1-3 and a single chart are the following:

- Table 1: Demographic data on 35,691 pregnant women receiving LNP/mRNA injections.

- Table 2: Reactogenicity data from four subgroups, Pfizer 1 N = 9,052, Pfizer 2 N = 6,638, Moderna 1 N = 7,930 and Moderna 2 N = 5,635.
- Figure 1: A plot of the reactogenicity data from an unspecified group other than they completed a day 1 survey.
- Table 3: Age brackets, race and ethnic identity, timing of the first eligible dose, and incidence of Covid-19 during pregnancy for various non-identified subsets of 3,958 registrants in the pregnancy Registry.
- Tables 1-3 combined with Chart 1 have no value informing the reader as to how often spontaneous abortion, stillbirth, preterm birth, small size for gestational age, congenital deformity and neonatal death occur after first trimester inoculation with LNP/mRNA gene therapy products.

These large Tables and complex Charts may blunt the senses of some readers and obscure the shortcomings of the post EUA surveillance efforts by government health agencies.

Conclusions:

Remarkably, after approximately one year and the efforts of:

1. *21 authors and 47 members* of the CDC Covid-19 Response V-safe Pregnancy Registry Team in 22 divisions of the CDC and FDA reporting in Shimabukuro, et al.
2. *13 authors, 59 members* of the CDC Covid-19 Response V-safe Pregnancy Registry Team, now joined with colleagues from NIH, the US Department of Energy, the US Public Health Service, the National Institute for Occupational Health and Safety and the National institute of Environmental Health Sciences in Zauche, et al. **Exhibit X**.
3. *$13,922,163,000 in taxpayer money*. [https://www.cdc.gov/budget/documents/fy2021/FY-2021-CDC-Operating-Plan.pdf and https://www.fda.gov/media/149526/download]

*reliable and valid outcome data concerning the safety of LNP/mRNA experimental gene products in hundreds of thousands and perhaps millions of pregnant women and their babies was **not** produced. Furthermore, future reporting by these individuals or others from these agencies should not be accepted without access to raw data and complete description of the exact methodology used to obtain it.*

Exhibits

Exhibit I: Tracking CDC and FDA Publications in Calendar Year 2021

	Date	Journal	Lead Author	Title	Changes	# of Authors	# of Investigators	Description	Agency	# of Divisions	# in Pregnancy Registry	Completed Pregnancies	Live Births	Live birth to 2rd Trimester Injectes	Live Birth to 1st and 2nd Trimester Injectes	Spontaneous Abortions	SAb <13 wks.	Total Fetal Loss	Induced Abortions	Stillbirths	Periconception	1st Dose First Trimester	1st Dose Second Trimester	1st Dose Third Trimester	Pre Term	Small Size	Congenital Anomalies	Neonatal Death
1	4/21/2021 Print 4/22/21Online	NEJM: DOI:10.1056/NEJMoa2104983	Shimabukuro	Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons	Original in Print Version Only	21	47	V-safe and VERS Data review for first ten weeks	CDC and FDA	29	3958	827	712	700	12	104 of 827	96	115 of 827	10	1 of 725	92	1132	1714	1019	60 of 636 V before 37 wks	23 of 724	16 of 724	0 of 724
2	6/17/2021 Online version revised 9/8/2021 as reported 10/14/2021 No Original Print Version Located	NEJM;384:2273-82, DOI: 10.1056/NEJMoa2104983	Shimabukuro	Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons	Not available Except as 9/8/2021 Revised Version as Reported 10/14/2021	21	47	V-safe and VERS Data review for first ten weeks	CDC and FDA	29	3958	827	712	700	12	104 of 827	96	115 of 827	10	1 of 725	92	1132	1714	1019	60 of 636 V before 37 wks	23 of 724	16 of 724	0 of 724
3	9/8/2021 Online and Print Versions Not Located	NEJM: Unknown	Shimabukuro	Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons	1. P. 2273 "were pregnancy losses" 2. P. 2277 "(i.e. preterm, small size,...) 3. double dagger insert table 4 4. No Denominator for SAbs	21	47	V-safe and VERS Data review for first ten weeks	CDC and FDA	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	104	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported
4	10/14/2021 Online Notification of 9/8/2021 Corrections	NEJM: 385: 1536 DOI: 10.1056/NEJMc1536	Shimabukuro	Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons	1. P. 2273 "were pregnancy losses" 2. P. 2277 "(i.e. preterm, small size,...) 3. double dagger insert table 4 4. No Denominator for SAbs	21	47	V-safe and VERS Data review for first ten weeks	CDC and FDA	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	104	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported
5	Dec-21	Obstetrical & Gynecologic Survey Vol. 76, Issue 12, pp: 729-731	Shimabukuro	Preliminary Findings of mRNA Covid-19 Vaccine Safty in Pregnant Persons	Hybrid	21	Not Reported	V-safe and VERS Data review for first ten weeks	CDC and FDA	Not Reported	3958	827	712	Not Reported	Not Reported	Not Reported	Not Reported	115 of 827	Not Reported	Not Reported	92	1132	1714	1019	9.40%	3.20%	Not Reported	0
1	6/17/2021 Online Version in 10/14/2021 Revision	NEJM 384: 24 2342-2343	Riley	Editorial: mRNA Vaccines in Women	Original in Print Version Only, Online version is revised	1	1	Editorial	NEJM Editorial Board Member	N/A	3958	827	712	Not Reported	Not Reported	104/827 or 12.6%	Not Reported	Not Reported	1 of 827	Not Reported	Not Reported	28.6%	43.3%	25.7%	9.4%	3.2%	2.2%	0
2	9/8/21	NEJM: Unknown	Unknown	Revision of Riley Editorial	Cannot Locate	N/A	N/A	N/A	NEJM?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3	10/14/2021 Online Notification of 9/8/2021 Revisions	NEJM: 385:1536 DOI: 10.1056/NEJMx210017	Unknown	Revision of Riley Editorial	"...no proportion could be determined for the risk of spontaneous abortion among participants vaccinated before 20 weeks of gestations..."	Unknown	Unknown	Revision of Editorial	NEJM?	N/A	N/A	N/A	N/A	N/A	N/A	104	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1	10/14/2021 Online Version of Letters Published 9/8/2012 at NEJM.org	NEJM: 385:1535-1536 Unable to locate 9/8/2021 version	Sun	On Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons	PhD in Antwerp Questions Validity of 827 denominator and 12.6% SAbR because it includes 3rd Trimester Vaccinees	1	1	Correspondence Questioning Calculation of Spontaneous Abortion Rate	Diefidas Healthcare, Belgium	N/A	N/A	N/A	N/A	N/A	N/A	104 of 827 not valid for SAbR	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
2	10/14/2021 Online Version of Letters Published 9/8/2012 at NEJM.org	NEJM: 385:1535-1536 Unable to locate 9/8/2021 version	Mesny-Dolman	On Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons	Agrees with Sun, 827 is not a valid denominator; Table 4 in 6/17/21 Shimabukuro amended// refers to Zauche Update	3	3	Response to Sun	CDC	N/A	N/A	N/A	N/A	N/A	N/A	Offers new SAbR of 14.1% based on Zauche	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1	Research Square Preprint 08/09/2021	Research Square Preprint posted 8/9/2021 No Updates doi.org/10.21203/rs.3.rs-798175/v1	Zauche	Receipt of mRNA COVID-19 preconception and during pregnancy and risk of self-reported spontaneous abortions, CDC v-safe Vaccine pregnancy Registry 2020-21	Excluded SAbs before 6 weks	13	~62	Life table methods, confusing methodology	CDC FDA, NIH, US Dept of Energy, US Public Health Service, National Institute of Environmental health Sciences, UCSD	Many	2491 with 1 dose + 20 wks	Not Reported	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text
2	09/08/2021 Unable to locate	Letter	Zauche	Receipt of mRNA COVID-19 preconception and during pregnancy and risk of self-reported spontaneous abortions, CDC v-safe Vaccine pregnancy Registry 2020-22	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate	Unable to locate
3	10/14/2021 Online	NEJM 385:1533-1535 refers to Research Square, data in Supplement	Zauche	Receipt of mRNA Vaccines and Risk of Spontaneous Abortion	Cumulative risk	13	~62	Life table methods, confusing methodology	CDC FDA, NIH, US Dept of Energy, US Public Health Service, National Institute of Environmental health Sciences, UCSD	See Text	See Text	See Text	See Text	See Text	See Text	14.10%	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text	See Text

Exhibit II: Shimabukuro, et al. Publication Dates and Edits

1. **When was this study first published?**

A. Below is the first page of the June 17, 2021, version of Shimabukuro, et al. indicating a publication date of April 21, 2021, at NEJM.org. However, attempts to access the April 21, 2021, version online returns the June 17, 2021, version. A hard copy version of the *NEJM* article does exist.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 17, 2021 VOL. 384 NO. 24

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., Ashley N. Smoots, M.P.H., Caitlin J. Green, M.P.H., Charles Licata, Ph.D., Bicheng C. Zhang, M.S., Meghna Alimchandani, M.D., Adamma Mba-Jonas, M.D., Stacey W. Martin, M.S., Julianne M. Gee, M.P.H., and Dana M. Meaney-Delman, M.D., for the CDC v-safe COVID-19 Pregnancy Registry Team*

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.

RESULTS

A total of 35,691 v-safe participants 16 to 54 years of age identified as pregnant. Injection-site pain was reported more frequently among pregnant persons than among nonpregnant women, whereas headache, myalgia, chills, and fever were reported less frequently. Among 3958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy, of which 115 (13.9%) were pregnancy losses and 712 (86.1%) were live births (mostly among participants vaccinated in the third trimester). Adverse neonatal outcomes included preterm birth (in 9.4%) and small size for gestational age (in 3.2%); no neonatal deaths were reported. Although not directly comparable, calculated proportions of adverse pregnancy and neonatal outcomes in persons vaccinated against Covid-19 who had a completed pregnancy were similar to incidences reported in studies involving pregnant women that were conducted before the Covid-19 pandemic. Among 221 pregnancy-related adverse events reported to the VAERS, the most frequently reported event was spontaneous abortion (46 cases).

CONCLUSIONS

Preliminary findings did not show obvious safety signals among pregnant persons who received mRNA Covid-19 vaccines. However, more longitudinal follow-up, including follow-up of large numbers of women vaccinated earlier in pregnancy, is necessary to inform maternal, pregnancy, and infant outcomes.

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Shimabukuro at the Immunization Safety Office, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30329, or at tshimabukuro@cdc.gov.

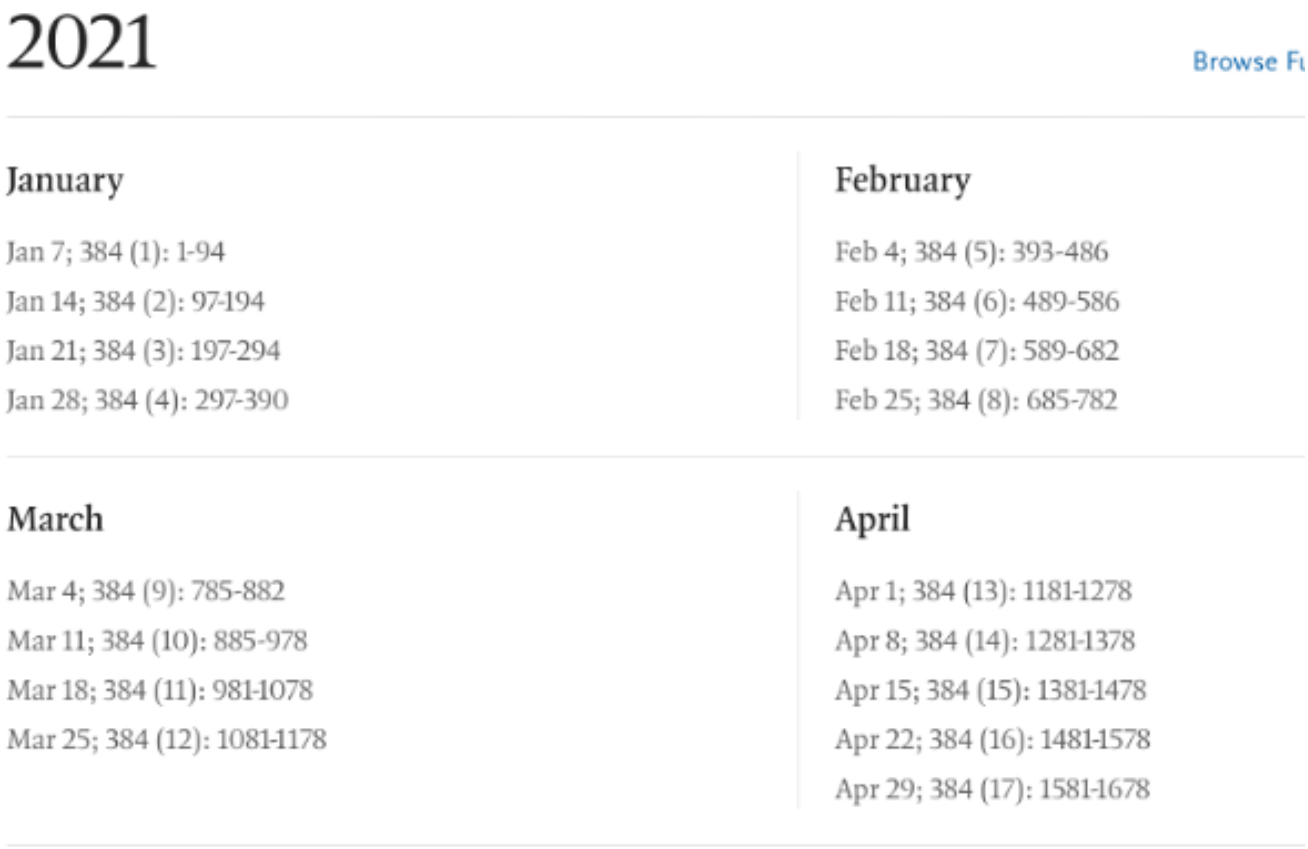
*The members of the CDC v-safe COVID-19 Pregnancy Registry Team are listed in the Supplementary Appendix, available at NEJM.org.

This article was published on April 21, 2021, and updated on September 8, 2021, at NEJM.org.

N Engl J Med 2021;384:2273-82.
DOI: 10.1056/NEJMoa2104983

Above: a recent online search for the April 21? April 22? article returns an article with the June 17, 2021, publication date.

B. There is no April 21, 2021, publication date listed in the *NEJM* Online Index. The closest date is April 22, 2021.



2021

Browse Fu

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Apr 29; 384 (17): 1581-1678

C. Online search for Table of Contents for April 21 or 22, 2021, *lists no such article*:
https://www.nejm.org/toc/nejm/384/15

Here it is in hard copy downloaded shortly after publication date April 21 or 22, 2021.

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 Odouyebo, 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., Ashley N. Smoots, M.P.H., Caitlin J. Green, M.P.H., Charles Licata, Ph.D., Bicheng C. Zhang, M.S., Meghna Alimchandani, M.D., Adamma Mba-Jonas, M.D., Stacey W. Martin, M.S., Julianne M. Gee, M.P.H., and Dana M. Meaney-Delman, M.D., for the CDC v-safe COVID-19 Pregnancy Registry Team*

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A total of 35,691 v-safe participants 16 to 54 years of age identified as pregnant. Injection-site pain was reported more frequently among pregnant persons than among nonpregnant women, whereas headache, myalgia, chills, and fever were reported less frequently. Among 3958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy, of which 115 (13.9%) resulted in a pregnancy loss and 712 (86.1%) resulted in a live birth (mostly among participants with vaccination in the third trimester). Adverse neonatal outcomes included preterm birth (in 9.4%) and small size for gestational age (in 3.2%); no neonatal deaths were reported. Although not directly comparable, calculated proportions of adverse pregnancy and neonatal outcomes in persons vaccinated against Covid-19 who had a completed pregnancy were similar to incidences reported in studies involving pregnant women that were conducted before the Covid-19 pandemic. Among 221 pregnancy-related adverse events reported to the VAERS, the most frequently reported event was spontaneous abortion (46 cases).

CONCLUSIONS

Preliminary findings did not show obvious safety signals among pregnant persons who received mRNA Covid-19 vaccines. However, more longitudinal follow-up, including follow-up of large numbers of women vaccinated earlier in pregnancy, is necessary to inform maternal, pregnancy, and infant outcomes.

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Shimabukuro at the Immunization Safety Office, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30329, or at tshimabukuro@cdc.gov.

*The members of the CDC v-safe COVID-19 Pregnancy Registry Team are listed in the Supplementary Appendix, available at NEJM.org.

This article was published on April 21, 2021, at NEJM.org.

DOI: 10.1056/NEJMoa2104983

D. April 21, June 17, September 8, October 14 – all 2021 – *NEJM* versions.

A hard copy of the April 21, 2021, report appears to be the original version of the June 17, 2021, publication. Currently, the June 17, 2021, version online was modified on September 8, 2021, but no online version for that date is currently available. The October 14, 2021, edition of *NEJM* acknowledges the September 8, 2021, revisions in the June 17, 2021, republication of the April 21, 2021, original.

E. September 8, 2021, corrections of the April 21, 2021, original Shimabukuro, et al. paper, republished online June 17, 2021, as reported in the October 14, 2021, online *NEJM* are presented below.

Author: *No Author Listed* dated October 14, 2021,
N Engl J Med 2021; 385:1536
DOI: 10.1056/NEJMx210016

1. **p. 2273 third sentence of the Abstract (Actually, the quote was in the fourth sentence.)**

Correction:
"Among 3958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy, of which ***115 (13.9%) were pregnancy losses*** and 712 (86.1%) were live births **(mostly among participants vaccinated in the third trimester)."**
Original:
rather than "…of which 115 (13.9%) ***resulted in a pregnancy loss*** and 712 (86.1%) resulted in a live birth (mostly among participants with vaccination in the third trimester)."

2. **Discussion section (p. 2277),** the parenthetical in the third sentence should have begun,

Correction:
"(i.e., preterm birth, small size, …,"
Original:
"(e.g., fetal loss, preterm birth, small size, …."

3. **Table 4 (p. 2280)**

Corrections:
Spontaneous abortion: <20 wk[15-17‡] current Table 4 after revisions.

The **"Published Incidence"** cell in the same row should have read
"Not applicable," rather than "10–26," and the
"V-safe Pregnancy Registry" cell should have read ***"104," rather than "104/827 (12.6)‡."***

4. **Double sword footnote on p. 2280 was added.**

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	*no./total no. (%)*
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk[15-17]‡	Not applicable	104

5. In the **Table 4 footnotes,** the following content **was next to the double dagger footnote:**
"***No denominator was available to calculate a risk estimate for spontaneous abortions,***
because at the time of this report
follow-up through 20 weeks was not yet available for 905 of the 1224 participants
vaccinated within 30 days before the first day of the last menstrual period or in the first trimester.
Furthermore, any risk estimate would need to account for gestational week–specific risk of spontaneous abortion."

"Updates" in June, September, October and December of 2021 provided *no new information* about the 35,691 pregnant women injected with LNP/mRNA in December 2020 thru February 2021 in V-safe or the 3958 injected pregnant women in the Pregnancy Registry. There should have been completion of pregnancy data on the pregnant women injected in the first 6 weeks by October and all of 10 weeks by December 2021 yet the December update (Obstetrical & Gynecological Survey, December 2021, 76, 12, 729-731) reported on only 827 completed pregnancies.

F. Current Status as of September 6, 2022
Shimabukuro, et al. September 6, 2022, version of the June 17, 2021, publication (downloaded August 22, 2022, and checked again on September 6, 2022)
A. Abstract in the September 6, 2022, version, page 2273:

"Among 3958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy, of which 115 *(13.9%) were pregnancy losses* and 712 (86.1%) were live births (mostly among participants vaccinated in the third trimester)."

The errors in this calculation are explained below:

- Numerator = 115 = 104 Spontaneous Abortions (< 20 weeks) + 1 Stillbirth (>20 weeks) + 10 medical abortions.
- Denominator = 827 = 127 first and second trimester cases + 700 third trimester cases

B. Text on p. 2276 in **the September 6, 2022, version**:
"Among 827 participants who had a completed pregnancy, the pregnancy resulted in a live birth in 712 (86.1%), in a ***spontaneous abortion in 104 (12.6%)*****,** in stillbirth in 1 (0.1%), and in other outcomes (induced abortion and ectopic pregnancy) in 10 (1.2%)."

The errors in this calculation are explained below:

- Numerator = 104 Spontaneous Abortions (less than 20 weeks)
- Denominator = 827 = 700 stillbirths in third trimester cases and 127 first and second trimester cases (spontaneous abortions – i.e., <20 weeks' gestation – plus stillbirths for >20 weeks in second trimester)

Table 4 double sword footnote, p. 2280:

"A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation. ***No denominator was available to calculate a risk estimate for spontaneous abortions, because at the time of this report***, follow-up through 20 weeks was not yet available for 905 of the 1224 participants vaccinated within 30 days before the first day of the last menstrual period or in the first trimester. Furthermore, any risk estimate would need to account for gestational week–specific risk of spontaneous abortion."

The corrections that currently exist in the June 17, 2021, version of the Shimabukuro, et al. document having been adjusted retroactively such that a reader today would not know the calculation of Spontaneous Abortion Rate had been dropped in a September 8, 2021, revision of the June 17, 2021, republication of the original April 21, 2021, document.

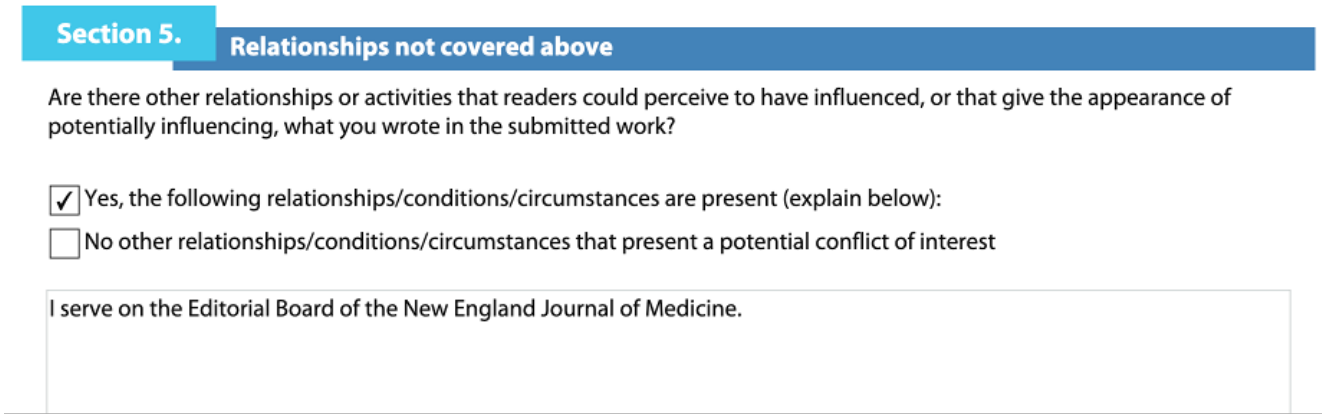
Exhibit III. Riley.

Editorial.
"mRNA Covid-19 Vaccines in Pregnant Women"
Laura E. Riley, MD,
N Engl J Med 2021; 384:2342-2343
DOI: 10.1056/NEJMe2107070
[https://www.nejm.org/doi/full/10.1056/NEJMe2107070]
June 17, 2021

Dr. Riley's editorial discussed the Shimabukuro, et al. paper that curiously appears in the same issue of *NEJM* as the Shimabukuro, et al. article itself. Was she responding to the April 2021 publication? This editorial was published on June 17, 2021. There were then two versions of the June 17, 2021, Shimabukuro et al. paper – the original and a version that was revised on September 8, 2021. Notification about the revision was made in the October 14, 2021, issue of NEJM.
Dr. Riley's bio:

"Laura E. Riley, MD, a renowned obstetrician who specializes in obstetric infectious disease, has been appointed Chair of the Department of Obstetrics and Gynecology at Weill Cornell Medicine and Obstetrician and Gynecologist-in-Chief at New York-Presbyterian/Weill Cornell Medical Center." [https://www.nyp.org/publications/professional-advances/gynecology/dr-laura-e-riley-new-chair-of-obstetrics-and]

Dr. Riley is a member of the Editorial Board of the *New England Journal of Medicine*.


Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

☑ Yes, the following relationships/conditions/circumstances are present (explain below):

☐ No other relationships/conditions/circumstances that present a potential conflict of interest

I serve on the Editorial Board of the New England Journal of Medicine.

Dr. Riley made the following statement in her editorial:

"It is notable that as of April 26, 2021, more than 100,000 pregnant women reported having received a Covid-19 vaccination and yet **only a small fraction (4.7%) have enrolled in the v-safe pregnancy registry**." [https://www.nejm.org/doi/full/10.1056/NEJMe2107070]

***Corrections of Dr. Riley's editorial dated September 8, 2021, were reported in the October 14, 2021, issue of* NEJM.** [https://pubmed.ncbi.nlm.nih.gov/34496193/ and https://www.nejm.org/doi/10.1056/NEJMx210017?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed]

mRNA Covid-19 Vaccines in Pregnant Women.
[https://pubmed.ncbi.nlm.nih.gov/34496193/]

[No authors listed]

N Engl J Med. 2021 Oct 14;385(16):1536. doi: 10.1056/NEJMx210017. Epub 2021 Sep 8. PMID: 34496193

No abstract available.

Corrections to the June 17, 2021, Riley editorial:

Original June 17, 2021:

"Among 827 registry participants who reported a completed pregnancy, the pregnancy resulted in a spontaneous abortion in **104 (12.6%)** and in stillbirth in 1 (0.1%); these percentages are well within the range expected as an outcome for this age group of persons whose other underlying medical conditions are unknown."

Revision #1

In the Results section of the Abstract (page 2273), the third sentence should have read:

"Among 827 registry participants who reported a completed pregnancy, 104 experienced spontaneous abortions and 1 had a stillbirth,"

rather than,

"…a completed pregnancy, the pregnancy resulted in a **spontaneous abortion in 104 (12.6%)** and in stillbirth in 1 (0.1%); these percentages are well within the range expected as an outcome for this age group of persons whose other underlying medical conditions are unknown."

Revision #2

In the first paragraph of the "Discussion" section (page 2277), the parenthetical in the third sentence should have begun:

"(i.e., preterm birth, small size, …,"

rather than

"(e.g., fetal loss, preterm birth, small size, …."

Revision #3

A. In Table 4 (page 2280), the double dagger symbol in the "Spontaneous abortion" row should have followed:

"Spontaneous abortion: <20 wk[15-17]."

Actual

"Spontaneous abortion: <20 wk[15-17] ‡"

B. The "Published Incidence" cell in the same row should have read "Not applicable," rather than "10–26,"

Actual

"Not applicable"

C. “V-safe Pregnancy Registry” cell should have read “104,”
rather than **“104/827 (12.6) ‡.”**
Actual
104

Revision #4

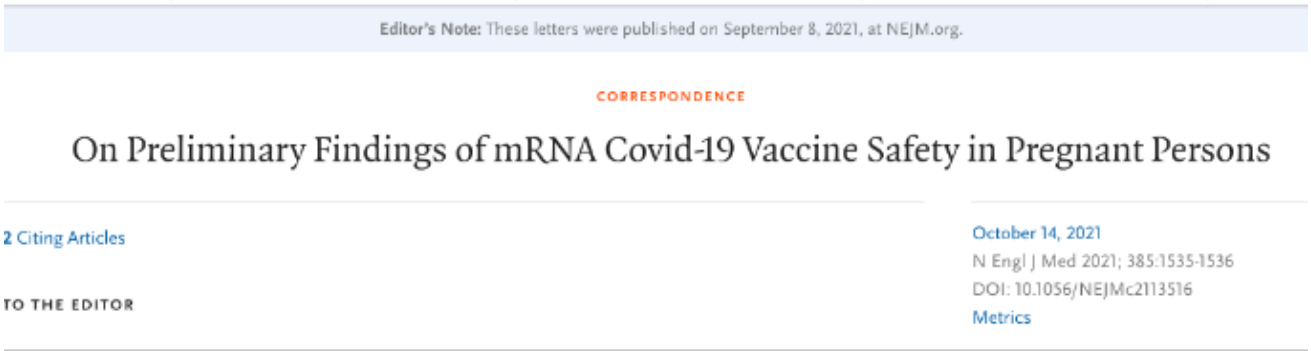
In the table footnotes, the following content should have been appended to the double dagger footnote:
“No denominator was available to calculate a risk estimate for spontaneous abortions, because at the time of this report, follow-up through 20 weeks was not yet available for 905 of the 1224 participants vaccinated within 30 days before the first day of the last menstrual period or in the first trimester. Furthermore, any risk estimate would need to account for gestational week–specific risk of spontaneous abortion.”

Actual:
“No denominator was available to calculate a risk estimate for spontaneous abortions, because at the time of this report, follow-up through 20 weeks was not yet available for 905 of the 1224 participants vaccinated within 30 days before the first day of the last menstrual period or in the first trimester. Furthermore, any risk estimate would need to account for gestational week–specific risk of spontaneous abortion.”

“The article is correct at NEJM.org.”

Exhibit IV: Hong Sun, PhD Correspondence, *NEJM* October 14, 2021.

Criticism
Dr. Hong Sun, PhD of Antwerp, Belgium, presented his objections to the calculated rate of spontaneous abortions in the June 17,2021, version. He spotted the error made in using the wrong denominator.


Editor's Note: These letters were published on September 8, 2021, at NEJM.org.

CORRESPONDENCE

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

2 Citing Articles

TO THE EDITOR

October 14, 2021
N Engl J Med 2021; 385:1535-1536
DOI: 10.1056/NEJMc2113516
Metrics

“As stated in the article, among the 827 participants with a completed pregnancy, 700 received their first eligible vaccine dose in the third trimester. ***These participants should be excluded from the calculation because they had already passed week 20 when they received the vaccination.*** The risk of spontaneous abortion should be determined on the basis of the group of participants who received

the vaccination before week 20 and were followed through week 20 or had an earlier pregnancy loss."

This letter was reportedly published on September 8, 2021, at NEJM.org.

Response of Dr. Dana M. Meaney-Delman, MD, et al. in the same October 14, 2021, issue of *NEJM*.

The authors' reply:

"Sun appropriately raises questions about the proportion of women reporting spontaneous abortion in our recent article. We agree that the denominator used in that proportion — 827 completed pregnancies — is not an appropriate denominator for the calculation of a risk estimate or rate.

The number of spontaneous abortions (104) reflects data reported by the participants as of March 30, 2021, during telephone follow-up. In this preliminary report, follow-up information was missing for the majority of pregnancies in which exposure to vaccination occurred in early pregnancy.

Among the 1224 women who had been vaccinated before conception or in the first trimester, follow-up through 20 weeks of gestation had been completed for only 204 pregnancies that were known to be ongoing and for 1 pregnancy that resulted in stillbirth.

Among the pregnancies that had not yet reached 20 weeks of gestation, there were 10 pregnancies with other outcomes before 20 weeks of gestation, including 8 ectopic pregnancies and 2 induced abortions.
For the other 905 pregnancies, follow-up had not occurred to establish whether these pregnancies were ongoing past 20 weeks of gestation.

We have amended Table 4 in our earlier publication and have clarified the text.

Subsequently, we completed telephone follow-up for the 905 pregnancies and enrolled additional persons in the v-safe pregnancy registry.

To determine the cumulative risk of spontaneous abortion from 6 to less than 20 weeks of gestation, we used life-table methods to perform an updated analysis, now reported in the *Journal*, involving 2456 women who received at least one dose of an mRNA Covid-19 vaccine before conception or before 20 weeks of gestation.[1]

The estimated risks (14.1% overall and 12.8% in age-standardized analyses) are consistent with the risks of spontaneous abortion reported in the general population.[1]

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This letter was published on September 8, 2021, at NEJM.org.
Zauche LH, Wallace B, Smoots AN, et al. Receipt of mRNA Covid-19 vaccines and risk of spontaneous abortion. *N Engl J Med* 2021;385:1533-1535.

Exhibit V. Zauche, et al. Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion

October 14, 2021
N Engl J Med 2021; 385:1533-1535
DOI: 10.1056/NEJMc2113891
[https://www.nejm.org/toc/nejm/385/16?query=article_issue_link]

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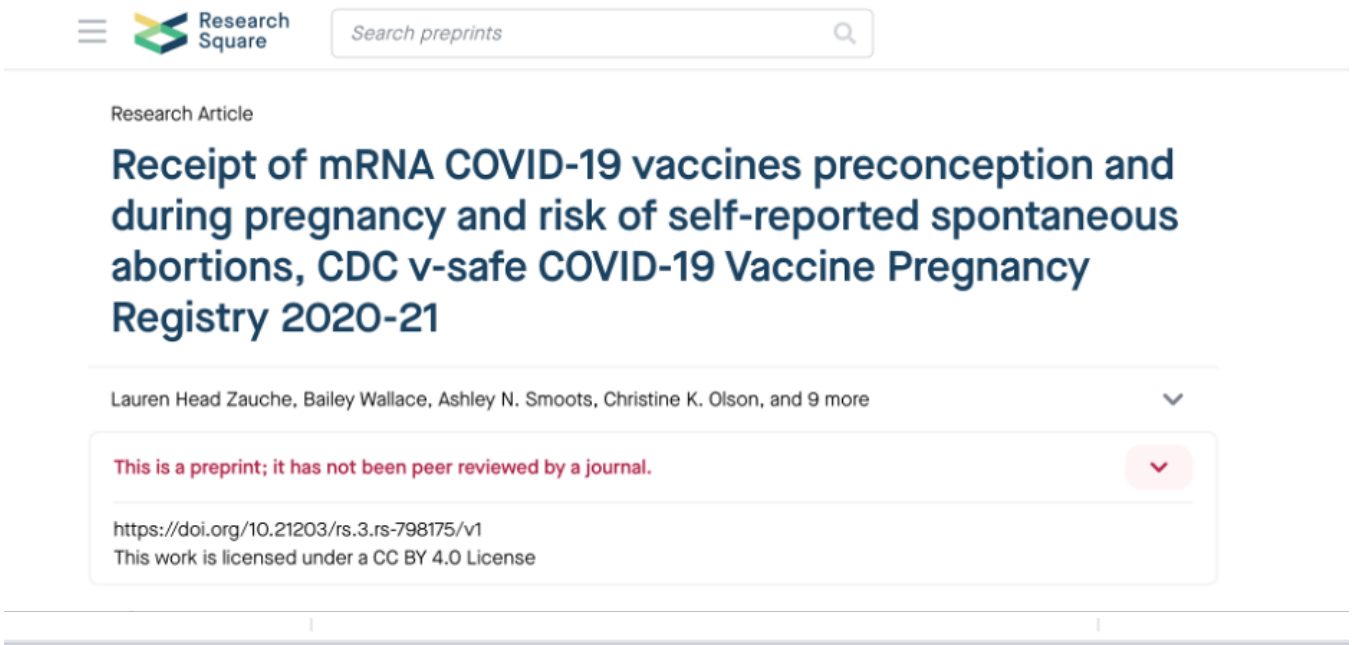
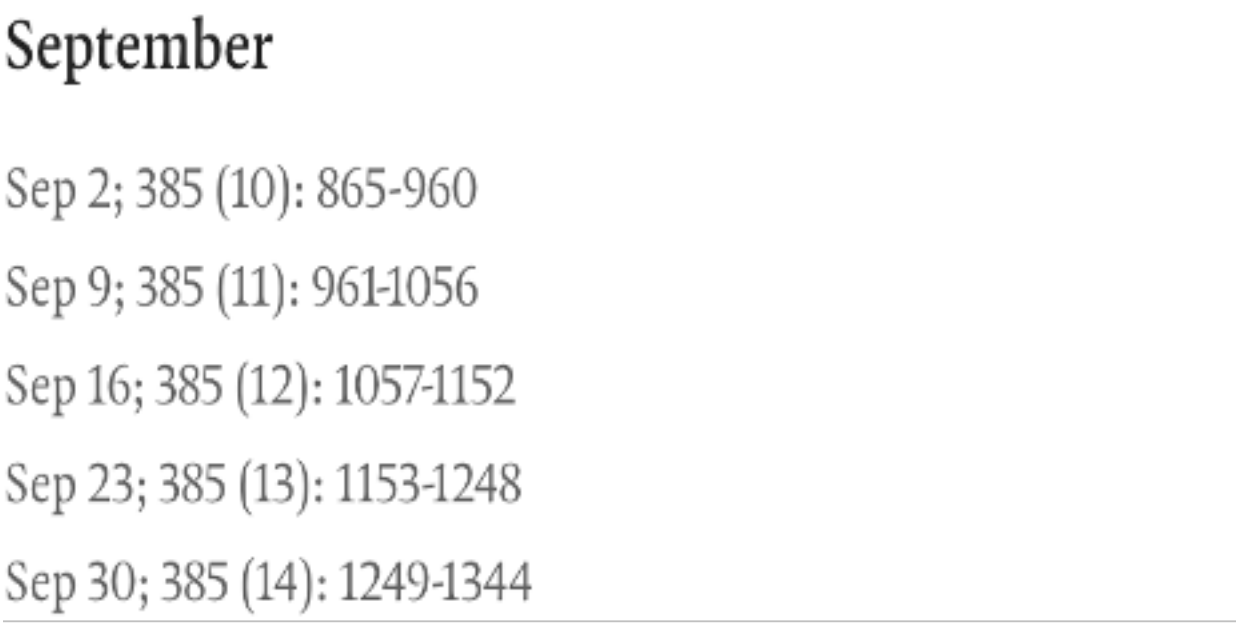
Editor's Note: This letter reportedly was published on **September 8, 2021**, at NEJM.org according to an Editor's Note at the top of the October 14, 2021, publication. There is no such paper listed at NEJM.org for September 8, 2021.



Editor's Note: This letter was published on September 8, 2021, at NEJM.org.

NEJM Volume 385 No. 11 dated September 9, 2021, has no such article, https://www.nejm.org/toc/nejm/385/11.



This two-and-a-half-page note appeared under the heading of "Correspondence" in the October 14, 2021, edition of the *NEJM*.

This report is an updated reporting of the CDC V-safe registry to determine the cumulative risk of spontaneous abortion from ***6 to less than 20 weeks of gestation***.

The authors' note:

"Although spontaneous abortion (pregnancy loss occurring at less than 20 weeks of gestation) is a common pregnancy outcome affecting 11 to 22% of recognized pregnancies (see Table S1 in the Supplementary Appendix, available with the full text of this letter at NEJM.org),[2-4] data to inform estimates of the risk of spontaneous abortion after receipt of an mRNA Covid-19 vaccine either before conception (30 days before the first day of the last menstrual period through 14 days after) or during pregnancy are limited." (Paragraph 1.)

The analysis included **singleton pregnancies** who received **one dose of an mRNA vaccine** before conception or before 20 weeks of gestation and who **did not have a pregnancy loss before six weeks of gestation.**

The second paragraph describes what the authors refer to as the use of "life table methods" to calculate the risk of spontaneous abortion. What is meant by this is not specified in the text other than a reference from the *British Medical Journal*. Magnus MC, Wilcox AJ, Morken N-H, Weinberg CR, Håberg SE. Role of maternal age and pregnancy history in risk of miscarriage: prospective registry based study. *BMJ* 2019;364: l869-l869.

"**Life table methods** were used to **calculate the cumulative risk of spontaneous abortion according to gestational week**, with appropriate **left truncation (i.e., with adjustment for gestational age at entry); data were right-censored** at the time of the most recent contact **for participants with ongoing pregnancies who were not contacted at 20 weeks of gestation or later** and at the time of the outcome for participants who reported pregnancy outcomes other than spontaneous abortion (induced abortions or ectopic or molar pregnancies) before 20 weeks of gestation."

"A total of 2456 participants who were enrolled in the CDC v-safe Covid-19 pregnancy registry met the inclusion criteria for this study;

1. 2022 participants reported ongoing pregnancies at 20 weeks of gestation,
2. 165 participants reported a spontaneous abortion
3. (154 participants before 14 weeks of gestation),
4. 65 participants with most recent contact during the first trimester could not be reached for second trimester follow-up,

5. 188 participants completed second trimester follow-up before 20 weeks of gestation,
6. 16 participants reported another pregnancy outcome before 20 weeks (induced abortion or ectopic or molar pregnancy) (Fig. S1).
7. Most participants were 30 years of age or older (77.3%), were non-Hispanic White (78.3%), and worked as health care personnel (88.8%).
8. Slightly more than half the participants (52.7%) had received the BNT162b2 vaccine (Pfizer–BioNTech) (Table S2).
9. The cumulative risk of spontaneous abortion from 6 to less than 20 weeks of gestation was 14.1% (95% confidence interval [CI], 12.1 to 16.1) in the primary analysis (Table 1) and 12.8% (95% CI, 10.8 to 14.8) in an analysis using direct maternal age–standardization to the reference population.
10. The cumulative risk of spontaneous abortion increased with maternal age (Table S3). In the sensitivity analysis, under the extreme assumption that all 65 participants with most recent contact during the first trimester had a spontaneous abortion, the cumulative risk of spontaneous abortion from 6 to less than 20 weeks of gestation was 18.8% (95% CI, 16.6 to 20.9); after age standardization, the cumulative risk was 18.5% (95% CI, 16.1 to 20.8)."

This perplexing analysis is presented in more detail in the Supplementary Appendix.
Curiously, this analysis was not cited in the December 2021 version of Shimabukuro, et al.
[https://journals.lww.com/obgynsurvey/Abstract/2021/12000/Preliminary_Findings_of_mRNA_COVID_19_Vaccine.7.aspx]

Exhibit VI. Shimabukuro, et al. Final Report for 2021.

Obstetrical & Gynecological Survey
December 2021 | Volume 76 | Issue 12 | pp: 729-731
doi: 10.1097/01.ogx.0000802676.57373.17
[https://journals.lww.com/obgynsurvey/Fulltext/2021/12000/Preliminary_Findings_of_mRNA_COVID_19_Vaccine.7.aspx]

OBSTETRICS: MEDICAL COMPLICATIONS OF PREGNANCY
Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons
Tom T. Shimabukuro

"Overall, 92 (2.3%) of participants received their first vaccination dose during the preconception period, 1132 (28.6%) in the first trimester, 1714 (43.3%) in the second trimester, and 1019 (25.7%) in the third trimester. In terms of adverse effects, injection site pain was described more among pregnant persons compared with nonpregnant women.

Headache, myalgia, chills, and fever were reported less often among pregnant persons compared with nonpregnant people. Of the 3958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy. ***Of these, 827 completed pregnancies, 115 (13.9%) resulted in a pregnancy***

loss, and 712 (86.1%) resulted in a live birth (mainly among participants with vaccination in the third trimester). *(p. 730)*

Adverse neonatal outcomes included preterm birth (in 9.4%) and small size for gestational age (in 3.2%); no neonatal deaths were reported. There were 221 pregnancy-related adverse events reported to VAERS, of which the most frequently reported event was spontaneous abortion (46 cases). No congenital anomalies were reported.

Of note, the proportions of adverse pregnancy and neonatal outcomes in the v-safe pregnancy database were similar to those published before the COVID-19 pandemic."

Exhibit VII: Changes in Table 4

April 2021/2022 *NEJM*, Shimabukuro:

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	*no./total no. (%)*
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk[15-17]	10–26	104/827 (12.6)‡
Stillbirth: ≥ 20 wk[18-20]	<1	1/725 (0.1)§
Neonatal outcome among live-born infants		
Preterm birth: <37 wk[21,22]	8–15	60/636 (9.4)¶
Small size for gestational age[23,24]‖	3.5	23/724 (3.2)
Congenital anomalies[25]**	3	16/724 (2.2)
Neonatal death[26]††	<1	0/724

* The populations from which these rates are derived are not matched to the current study population for age, race and ethnic group, or other demographic and clinical factors.

† Data on pregnancy loss are based on 827 participants in the v-safe pregnancy registry who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer–BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021, and who reported a completed pregnancy. A total of 700 participants (84.6%) received their first eligible dose in the third trimester. Data on neonatal outcomes are based on 724 live-born infants, including 12 sets of multiples.

‡ A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation.

§ The denominator includes live-born infants and stillbirths.

¶ The denominator includes only participants vaccinated before 37 weeks of gestation.

‖ Small size for gestational age indicates a birthweight below the 10th percentile for gestational age and infant sex according to INTERGROWTH-21st growth standards (http://intergrowth21.ndog.ox.ac.uk). These standards draw from an international sample including both low-income and high-income countries but exclude children with coexisting conditions and malnutrition. They can be used as a standard for healthy children growing under optimal conditions.

** Values include only major congenital anomalies in accordance with the Metropolitan Atlanta Congenital Defects Program 6-Digit Code Defect List (www.cdc.gov/ncbddd/birthdefects/macdp.html); all pregnancies with major congenital anomalies were exposed to Covid-19 vaccines only in the third trimester of pregnancy (i.e., well after the period of organogenesis).

†† Neonatal death indicates death within the first 28 days after delivery.

June 17, 2021, probably after the September 8, 2021, revision:

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	*no./total no. (%)*
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk[15-17]‡	Not applicable	104
Stillbirth: ≥ 20 wk[18-20]	<1	1/725 (0.1)§
Neonatal outcome among live-born infants		
Preterm birth: <37 wk[21,22]	8–15	60/636 (9.4)¶
Small size for gestational age[23,24]‖	3.5	23/724 (3.2)
Congenital anomalies[25]**	3	16/724 (2.2)
Neonatal death[26]††	<1	0/724

* The populations from which these rates are derived are not matched to the current study population for age, race and ethnic group, or other demographic and clinical factors.
† Data on pregnancy loss are based on 827 participants in the v-safe pregnancy registry who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer–BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021, and who reported a completed pregnancy. A total of 700 participants (84.6%) received their first eligible dose in the third trimester. Data on neonatal outcomes are based on 724 live-born infants, including 12 sets of multiples.
‡ A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation. No denominator was available to calculate a risk estimate for spontaneous abortions, because at the time of this report, follow-up through 20 weeks was not yet available for 905 of the 1224 participants vaccinated within 30 days before the first day of the last menstrual period or in the first trimester. Furthermore, any risk estimate would need to account for gestational week–specific risk of spontaneous abortion.
§ The denominator includes live-born infants and stillbirths.
¶ The denominator includes only participants vaccinated before 37 weeks of gestation.
‖ Small size for gestational age indicates a birthweight below the 10th percentile for gestational age and infant sex according to INTERGROWTH-21st growth standards (http://intergrowth21.ndog.ox.ac.uk). These standards draw from an international sample including both low-income and high-income countries but exclude children with coexisting conditions and malnutrition. They can be used as a standard for healthy children growing under optimal conditions.
** Values include only major congenital anomalies in accordance with the Metropolitan Atlanta Congenital Defects Program 6-Digit Code Defect List (www.cdc.gov/ncbddd/birthdefects/macdp.html); all pregnancies with major congenital anomalies were exposed to Covid-19 vaccines only in the third trimester of pregnancy (i.e., well after the period of organogenesis).
†† Neonatal death indicates death within the first 28 days after delivery.

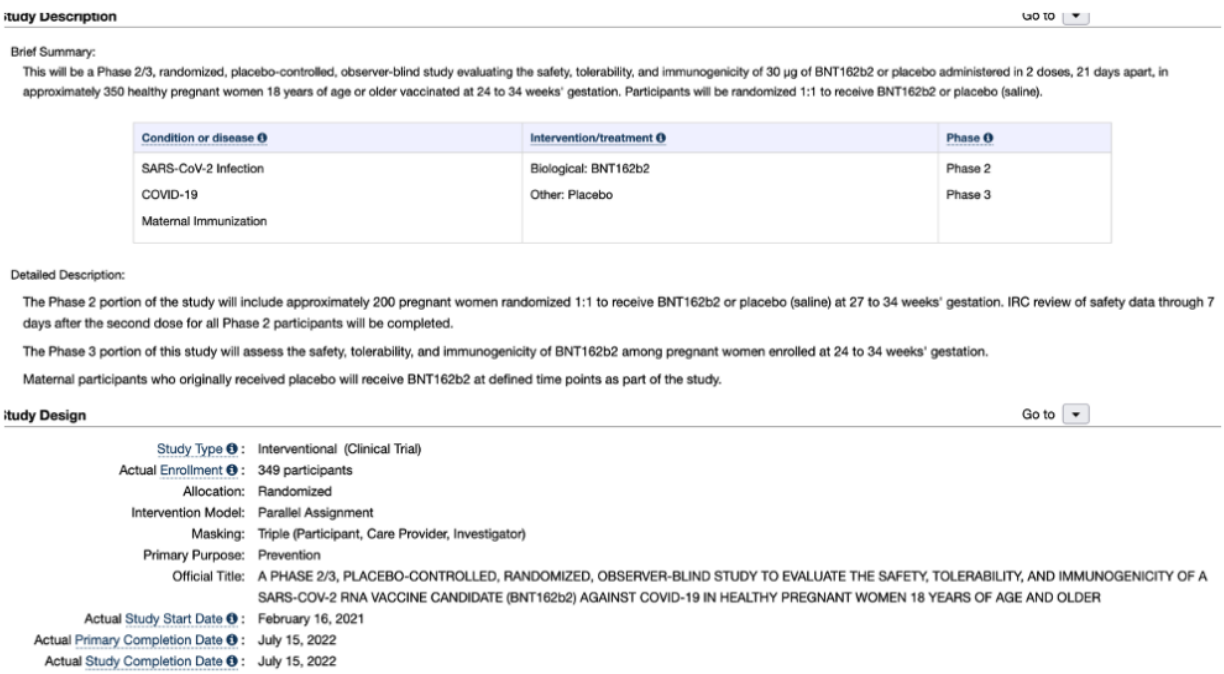
Exhibit VIII: Ongoing clinical trials completed July 15, 2022, with no published results as of September 5, 2022.

No Study Results Posted on ClinicalTrials.gov for this Study

About Study Results Reporting on ClinicalTrials.gov

Recruitment Status ℹ :	Completed
Actual Primary Completion Date ℹ :	July 15, 2022
Actual Study Completion Date ℹ :	July 15, 2022

This will be a Phase 2/3, randomized, placebo-controlled, observer-blind study evaluating the safety, tolerability, and immunogenicity of 30 µg of BNT162b2 or placebo administered in 2 doses, 21 days apart, in approximately 350 healthy pregnant women 18 years of age or older **vaccinated at 24 to 34 weeks' gestation.** Participants will be randomized 1:1 to receive BNT162b2 or placebo (saline).



Study Description

Go to

Brief Summary:

This will be a Phase 2/3, randomized, placebo-controlled, observer-blind study evaluating the safety, tolerability, and immunogenicity of 30 µg of BNT162b2 or placebo administered in 2 doses, 21 days apart, in approximately 350 healthy pregnant women 18 years of age or older vaccinated at 24 to 34 weeks' gestation. Participants will be randomized 1:1 to receive BNT162b2 or placebo (saline).

Condition or disease	Intervention/treatment	Phase
SARS-CoV-2 Infection	Biological: BNT162b2	Phase 2
COVID-19	Other: Placebo	Phase 3
Maternal Immunization		

Detailed Description:

The Phase 2 portion of the study will include approximately 200 pregnant women randomized 1:1 to receive BNT162b2 or placebo (saline) at 27 to 34 weeks' gestation. IRC review of safety data through 7 days after the second dose for all Phase 2 participants will be completed.

The Phase 3 portion of this study will assess the safety, tolerability, and immunogenicity of BNT162b2 among pregnant women enrolled at 24 to 34 weeks' gestation.

Maternal participants who originally received placebo will receive BNT162b2 at defined time points as part of the study.

Study Design

Go to

Study Type:	Interventional (Clinical Trial)
Actual Enrollment:	349 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Triple (Participant, Care Provider, Investigator)
Primary Purpose:	Prevention
Official Title:	A PHASE 2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF A SARS-COV-2 RNA VACCINE CANDIDATE (BNT162b2) AGAINST COVID-19 IN HEALTHY PREGNANT WOMEN 18 YEARS OF AGE AND OLDER
Actual Study Start Date:	February 16, 2021
Actual Primary Completion Date:	July 15, 2022
Actual Study Completion Date:	July 15, 2022

[https://clinicaltrials.gov/ct2/show/NCT04754594?term=BNT162b2&draw=2&rank=10]

Exhibit IX: Obfuscation

Table 1. Characteristics of Persons Who Identified as Pregnant in the V-safe Surveillance System and Received an mRNA Covid-19 Vaccine.*

Characteristic	Pfizer–BioNTech Vaccine	Moderna Vaccine	Total
	number (percent)		
Total	19,252 (53.9)	16,439 (46.1)	35,691 (100)
Age at first vaccine dose			
16–19 yr	23 (0.1)	36 (0.2)	59 (0.2)
20–24 yr	469 (2.4)	525 (3.2)	994 (2.8)
25–34 yr	11,913 (61.9)	9,960 (60.6)	21,873 (61.3)
35–44 yr	6,002 (31.2)	5,011 (30.5)	11,013 (30.9)
45–54 yr	845 (4.4)	907 (5.5)	1,752 (4.9)
Pregnancy status			
Pregnant at time of vaccination	16,522 (85.8)	14,365 (87.4)	30,887 (86.5)
Positive pregnancy test after vaccination	2,730 (14.2)	2,074 (12.6)	4,804 (13.5)
Race and ethnic group†			
Participants with available data	14,320	13,232	27,552
Non-Hispanic White	10,915 (76.2)	9,982 (75.4)	20,897 (75.8)
Hispanic	1,289 (9.0)	1,364 (10.3)	2,653 (9.6)
Non-Hispanic Asian	972 (6.8)	762 (5.8)	1,734 (6.3)
Non-Hispanic Black	371 (2.6)	338 (2.6)	709 (2.6)
Non-Hispanic multiple races	315 (2.2)	292 (2.2)	607 (2.2)
Non-Hispanic other race	76 (0.5)	56 (0.4)	132 (0.5)
Non-Hispanic American Indian or Alaska Native	40 (0.3)	54 (0.4)	94 (0.3)
Non-Hispanic Native Hawaiian or other Pacific Islander	33 (0.2)	31 (0.2)	64 (0.2)
Unknown race or unknown ethnic group	309 (2.2)	353 (2.7)	662 (2.4)

* Shown are the characteristics of v-safe participants 16 to 54 years of age who identified as

Table 2. Frequency of Local and Systemic Reactions Reported on the Day after mRNA Covid-19 Vaccination in Pregnant Persons.*

Reported Reaction	Pfizer–BioNTech Vaccine		Moderna Vaccine		Total	
	Dose 1 (N=9052)	Dose 2 (N=6638)	Dose 1 (N=7930)	Dose 2 (N=5635)	Dose 1 (N=16,982)	Dose 2 (N=12,273)
	number (percent)					
Injection-site pain	7602 (84.0)	5886 (88.7)	7360 (92.8)	5388 (95.6)	14,962 (88.1)	11,274 (91.9)
Fatigue	2406 (26.6)	4231 (63.7)	2616 (33.0)	4541 (80.6)	5,022 (29.6)	8,772 (71.5)
Headache	1497 (16.5)	3138 (47.3)	1581 (19.9)	3662 (65.0)	3,078 (18.1)	6,800 (55.4)
Myalgia	795 (8.8)	2916 (43.9)	1167 (14.7)	3722 (66.1)	1,962 (11.6)	6,638 (54.1)
Chills	254 (2.8)	1747 (26.3)	442 (5.6)	2755 (48.9)	696 (4.1)	4,502 (36.7)
Fever or felt feverish	256 (2.8)	1648 (24.8)	453 (5.7)	2594 (46.0)	709 (4.2)	4,242 (34.6)
Measured temperature ≥38°C	30 (0.3)	315 (4.7)	62 (0.8)	664 (11.8)	92 (0.5)	979 (8.0)
Nausea	492 (5.4)	1356 (20.4)	638 (8.0)	1909 (33.9)	1,130 (6.7)	3,265 (26.6)
Joint pain	209 (2.3)	1267 (19.1)	342 (4.3)	1871 (33.2)	551 (3.2)	3,138 (25.6)
Injection-site swelling	318 (3.5)	411 (6.2)	739 (9.3)	1051 (18.7)	1,057 (6.2)	1,462 (11.9)
Abdominal pain	117 (1.3)	316 (4.8)	160 (2.0)	401 (7.1)	277 (1.6)	717 (5.8)
Injection-site redness	160 (1.8)	169 (2.5)	348 (4.4)	491 (8.7)	508 (3.0)	660 (5.4)
Diarrhea	178 (2.0)	277 (4.2)	189 (2.4)	332 (5.9)	367 (2.2)	609 (5.0)
Vomiting	82 (0.9)	201 (3.0)	77 (1.0)	357 (6.3)	159 (0.9)	558 (4.5)
Injection-site itching	103 (1.1)	109 (1.6)	157 (2.0)	193 (3.4)	260 (1.5)	302 (2.5)
Rash	20 (0.2)	18 (0.3)	22 (0.3)	18 (0.3)	42 (0.2)	36 (0.3)

* Shown are solicited reactions in v-safe participants 16 to 54 years of age who identified as pregnant and who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer–BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021.

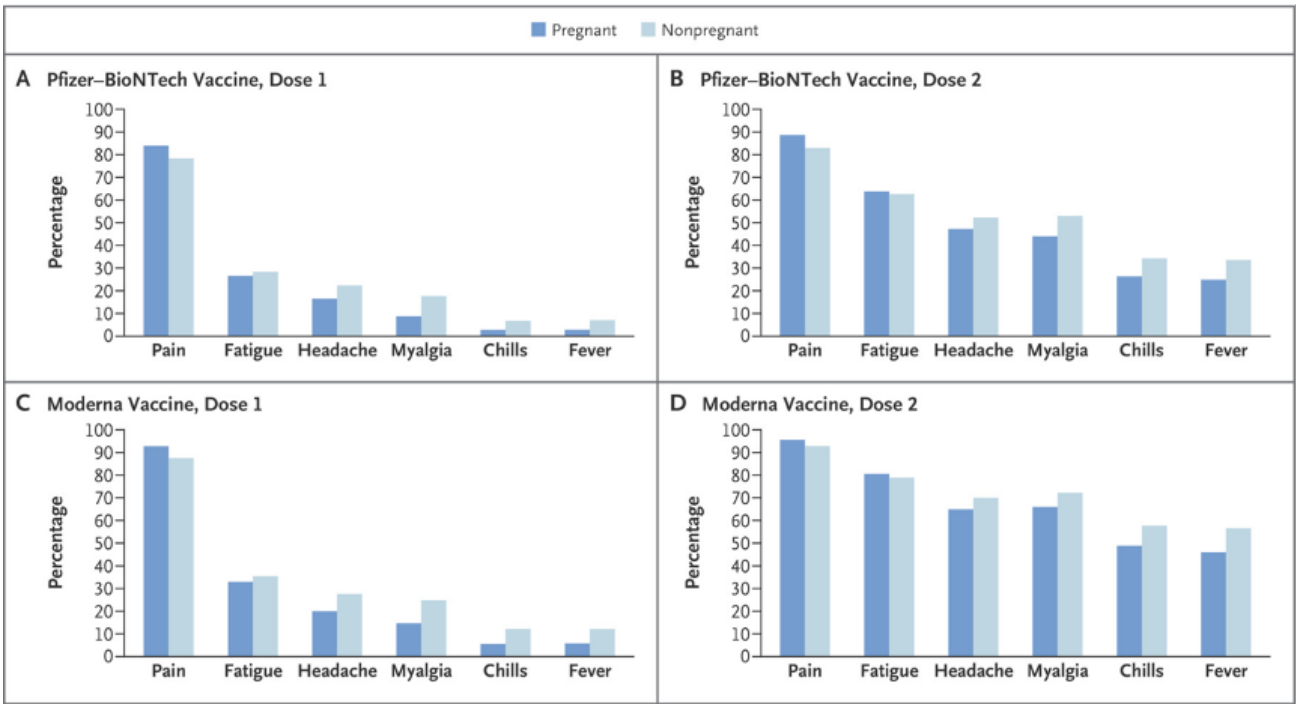


Table 3. Characteristics of V-safe Pregnancy Registry Participants.*

Characteristic	Pfizer–BioNTech Vaccine	Moderna Vaccine	Total
	number (percent)		
Total	2136 (54.0)	1822 (46.0)	3958 (100)
Age at first vaccine dose†			
20–24 yr	17 (0.8)	19 (1.0)	36 (0.9)
25–34 yr	1335 (62.5)	1238 (67.9)	2573 (65.0)
35–44 yr	777 (36.4)	560 (30.7)	1337 (33.8)
45–54 yr	7 (0.3)	5 (0.3)	12 (0.3)
Race and ethnic group‡			
Non-Hispanic White	1663 (77.9)	1463 (80.3)	3126 (79.0)
Hispanic	164 (7.7)	151 (8.3)	315 (8.0)
Non-Hispanic Asian	225 (10.5)	138 (7.6)	363 (9.2)
Non-Hispanic Black	24 (1.1)	26 (1.4)	50 (1.3)
Non-Hispanic multiple races	42 (2.0)	30 (1.6)	72 (1.8)
Non-Hispanic American Indian or Alaskan Native	5 (0.2)	1 (0.1)	6 (0.2)
Non-Hispanic Native Hawaiian or other Pacific Islander	6 (0.3)	3 (0.2)	9 (0.2)
Missing data or participant declined to answer	7 (0.3)	10 (0.5)	17 (0.4)
Timing of first eligible dose			
Periconception: within 30 days before last menstrual period	55 (2.6)	37 (2.0)	92 (2.3)
First trimester: <14 wk	615 (28.8)	517 (28.4)	1132 (28.6)
Second trimester: ≥14 and <28 wk	932 (43.6)	782 (42.9)	1714 (43.3)
Third trimester: ≥28 wk	533 (25.0)	486 (26.7)	1019 (25.7)
Missing data	1 (<0.1)	0	1 (<0.1)
Covid-19 infection during pregnancy			
No Covid-19 infection	2084 (97.6)	1779 (97.6)	3863 (97.6)
Before vaccination	32 (1.5)	24 (1.3)	56 (1.4)
≤14 days after first eligible dose of vaccination	3 (0.1)	7 (0.4)	10 (0.3)
>14 days after first eligible dose of vaccination	9 (0.4)	3 (0.2)	12 (0.3)
Missing data	8 (0.4)	9 (0.5)	17 (0.4)

* Shown are registry participants who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer–BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021. Percentages may not total 100 because of rounding.

† The v-safe pregnancy registry is only enrolling pregnant persons 18 years of age or older; at the time of this analysis, no participants were younger than 20 years of age.

‡ Race and ethnic group were reported by the participants.

Exhibit X: Authors and Investigators

I declare once again, as I did in the presence of the court: I detest as the greatest of crimes the horrors which were perpetrated against the Jews and think it right that the initiators of these terrible deeds will stand trial before the law now and in the future.

Notwithstanding, there is a need to draw a line between the leaders responsible and the people like me forced to serve as mere instruments in the hands of the leaders. I was not a responsible leader, and as such do not feel myself guilty.

Adolf Eichmann, May 29, 1962
[https://www.nytimes.com/2016/01/28/world/middleeast/adolf-eichmann-letter-to-israel-president.html?_r=0]

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Report 38: "Pfizer's EUA Granted Based on Fewer Than 0.4% of Clinical Trial Participants. FDA Ignored Disqualifying Protocol Deviations to Grant EUA." by Jeyanthi Kunadhasan, MD, FANZCA; Ed Clark, MSE; and Chris Flowers, MD – Team 3.

So much has been written about the pivotal Pfizer Trial for COVID-19 (C4591001), that it is sometimes hard to remember that the 'primary evaluable efficacy' analysis [Follman DA, 2007) *Follmann, D.A. (2007).* Primary Efficacy Endpoint. *Wiley Encyclopedia of Clinical Trials*. https://onlinelibrary.wiley.com/doi/10.1002/9780471462422.eoct341], was granted on the results of 170 subjects out of a trial that enrolled nearly 44,000 people.

What is a Clinical Trial?

A clinical trial is a method used to test a hypothesis and, in context, to determine whether an intervention is safe and effective. As a result, clinical trials are usually heavily monitored, and the protocol (i.e., instructions) for a trial must be followed to the letter so its trial participants (a.k.a., "subjects" or "patients") can rely on its conclusions. Protocol deviations – not following the instructions – lead to subjects being excluded from a trial and not included for analysis. Generally, any major modifications of the primary endpoint definitions or their analyses will also be reflected in a protocol amendment.

Once a primary endpoint is selected, statistical methods of analysis to test the primary hypothesis can be determined and sample size calculations can be performed to ensure the trial is properly powered. Because of the key role of the primary endpoint in the design and analysis of a trial, it is critical that it be chosen carefully. A primary efficacy endpoint must be precisely specified in advance and should *(1)* address the primary objective, *(2)* be ascertainable in all patients, *(3)* be "fair" to each study arm, *(4)* have demonstrated or accepted relevance for the population and intervention(s) of the trial, and *(5)* be sensitive to meaningful changes in a patient's health. The Statistical Analyses Plan (SAP) would also have been developed and finalized before the database 'lock' for any of the planned analyses. It would describe the participant populations to be included and the procedures for accounting for missing, unused, and spurious data.

This was a trial of a brand-new drug and platform of delivery. As such, the first phase of the trial was essentially an exercise to identify the preferred vaccine candidate, dose level, number of doses, *and* schedule of administration (appropriate dosing interval). The original protocol, dated 15 April 2020, outlined this, and it remained the same until the fourth protocol amendment dated 30 June 2020.

How was the *original* Pfizer Clinical Trial designed?

The study design described in the protocol released on 15 April 2020 [*A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA*

VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS. (901AD)32, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf] described a Phase 1/2, randomized, placebo-controlled, observer-blind, dose-finding, and vaccine candidate–selection study in healthy adults. The study, at that point, would evaluate the safety, tolerability, immunogenicity, and potential efficacy of up to four different SARS-CoV-2 RNA vaccine candidates against COVID-19:

- As a two-dose (separated by 21 or 60 days) or single-dose schedule
- At up to three different dose levels
- In three age groups
    - 18 to 55 years of age
    - 65 to 85 years of age
    - 18 to 85 years of age [stratified as ≤55 or >55 years of age]

This trial had many endpoints in terms of safety, tolerability, and immunogenicity. However, the Food and Drug Administration granted Emergency Use Authorization (EUA) on the endpoint of efficacy, evaluating BNT162 vaccines against contracting COVID-19.

The evaluable population was defined as all eligible, randomized participants who received vaccination as randomized within the *predefined window*, had the efficacy measurement after the last dose of study intervention, and had no other major protocol deviations as determined by the clinician. The efficacy measurement was getting COVID-19 illness and would be assessed by doing a mid-turbinate (nasal) swab in a symptomatic patient.

The language of the original protocol describing the second dose of the vaccine stated implicitly that Dose 2 could be either 19 to 23 days or 56 to 70 days after Visit 1, and that the *window* for Visit 2 was dependent on the dosing schedule that would be selected for Stage 3. This was at the same time they were deciding between either single dosing or a two-dose regimen which could be 21 or 60 days apart (with a range of approved variance) for both regimens.

The issues highlighted continued until protocol Amendment 4, dated 30 June 2020.

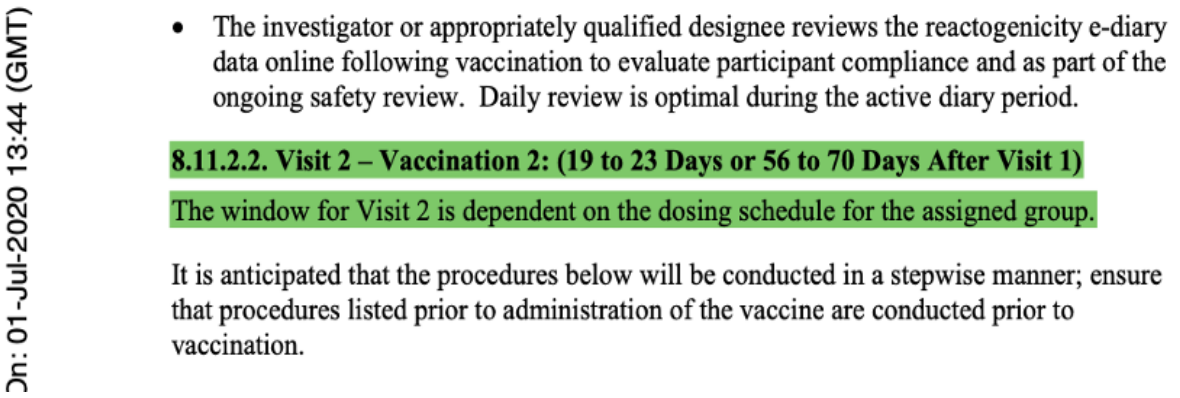
Below is an example of the expected flow of that protocol.

1.3.2. Stage 1 Nonsentinel Cohorts and Stage 2 Cohorts

An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 con
between Visit 1 (Vaccination 1) and Visit 7 (24-month follow-up visit) that COVID-19

Visit Number	1	2	3	4	5
Visit Description	**Vaccination 1**	**Vaccination 2**	**2-Week Follow-up Visit**	**1-Month Follow-up Visit**	**6-Month Follow-up Visit**
Visit Window (Days)	**Day 1**	**19 to 23 Days After Visit 1 or 56 to 70 Days After Visit 1[b]**	**12 to 16 Days After Visit 2**	**28 to 35 Days After Visit 2**	**154 to 168 Days After Visit 2**
Obtain informed consent	X				
Assign participant number	X				
Obtain demography and medical history data	X				
Perform physical examination	X				
Measure vital signs	X				
Perform urine pregnancy test (if appropriate)	X	X			
Collect nonstudy vaccine information	X	X	X	X	X
Collect prohibited medication use		X	X	X	X
Confirm eligibility	X	X			
Measure temperature (body)	X	X			
Review temporary delay criteria	X	X			
Confirm use of contraceptives (if appropriate)	X	X	X	X	
Obtain randomization number and study intervention allocation	X				

[https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, p. 1703.]



Dn: 01-Jul-2020 13:44 (GMT)

- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

8.11.2.2. Visit 2 – Vaccination 2: (19 to 23 Days or 56 to 70 Days After Visit 1)

The window for Visit 2 is dependent on the dosing schedule for the assigned group.

It is anticipated that the procedures below will be conducted in a stepwise manner; ensure that procedures listed prior to administration of the vaccine are conducted prior to vaccination.

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, p. 135]

What happened to the dose and interval between doses by the start of the Phase 3 study?

Protocol Amendment 5 was extremely important as it was the last protocol amendment made prior to the commencement of the Phase 3 Trial on 27 July 2020. Dated 24 July 2020, it clearly stated that following regulatory feedback, a single vaccine candidate administered *as two doses 21 days apart*, would be studied in Phase 2/3 and that the vaccine candidate would be *BNT162b2 at a dose of 30 µg*. The protocol was changed to reflect this as evidenced below.

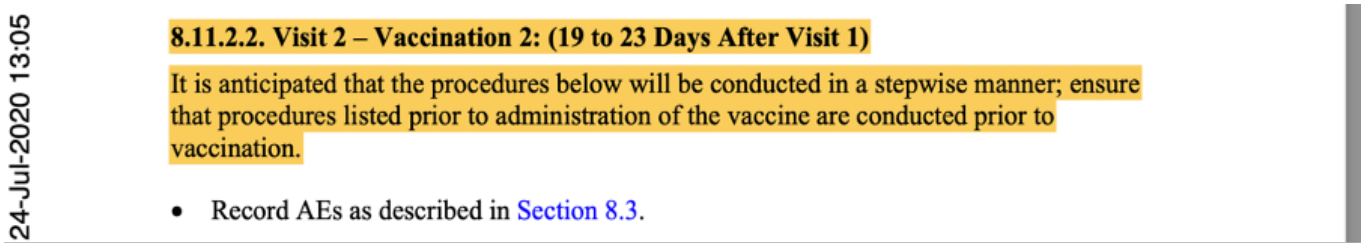
1.3.2. Phase 2/3

An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 convalescent visit are required at any time between Visit 1 (Vaccination 1) and Visit 6 (24-month follow-up visit) that COVID-19 is suspected.

Visit Number	1	2	3	4	5	6	Unplanned	Unplanned
Visit Description	**Vaccination 1**	**Vaccination 2**	**1-Month Follow-up Visit**	**6-Month Follow-up Visit**	**12-Month Follow-up Visit**	**24-Month Follow-up Visit**	**Potential COVID-19 Illness Visit[a]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**Day 1[b]**	**19 to 23 Days After Visit 1**	**28 to 35 Days After Visit 2**	**154 to 168 Days After Visit 2**	**350 to 378 Days After Visit 2**	**714 to 742 Days After Visit 2**	**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
Obtain informed consent	X							
Assign participant number	X							
Obtain demography and medical history data	X							
Perform clinical assessment[c]	X							
Measure height and weight	X							
Perform urine pregnancy test (if appropriate)	X	X						
Collect nonstudy vaccine information	X	X	X	X				
Collect prohibited medication use		X	X	X	X	X	X	X
Confirm eligibility	X	X						
Measure temperature (body)	X	X						
Review temporary delay criteria	X	X						
Confirm use of contraceptives (if appropriate)	X	X	X					
Collect blood sample for immunogenicity assessment	~25 mL		~25 mL	~25 mL	~25 mL	~25 mL		~50 mL
Obtain nasal (midturbinate) swab	X	X					X	
Obtain randomization number and study intervention allocation	X							
Administer study intervention	X	X						

[https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, p. 1564.]

The description of Visit 2 for the trial participants changed, confirming the dosing schedule had been set at 30 µg with a 21-day dosing interval. The 60-day dosing interval had been discarded. Pfizer settled on the dosing interval window prior to the trial starting, thus seeming to have settled on a predefined window.



[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, p. 1623.]

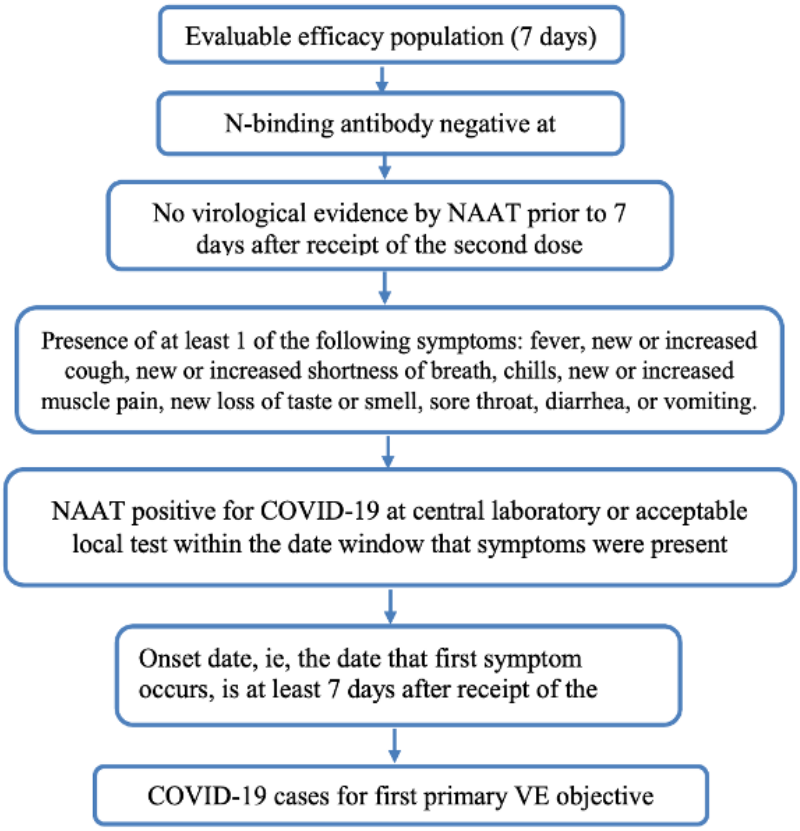
How would vaccine effectiveness be assessed?

If one wants to determine the effectiveness of a treatment, he or she has to follow the subjects throughout their involvement in the study through surveillance for potential COVID infection. If a participant developed acute respiratory illness, for the purposes of the study he or she would be considered to potentially have COVID illness. Participants were advised to contact the site for an in-person or tele-health visit if such symptoms presented. Nasal (mid-turbinate) swabs would be taken as part of this assessment. The diagnosis would be made based on a positive swab and the presence of at least one symptom from a symptoms list found in the protocol.

Below is a flowchart obtained from the Statistical Analysis Plan [*Protocol C4591001 A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS Statistical Analysis Plan (SAP) (GMT). (n.d.),* https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-fa-interim-sap.pdf] which clearly outlines those subjects who would qualify for the Primary Efficacy Analysis and, thus, qualify to be part of the evaluable population and be part of the 170 patients on which the EUA was granted.

Flowchart

1. The flowchart for deriving the COVID-19 cases included below for the first primary endpoints in evaluable efficacy participants with no serological or virological evidence of past SARS-CoV-2 infection:



Flowchart from Statistical Analysis Plan (SAP) – p. 58.

[https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-fa-interim-sap.pdf]

How did they decide which subjects qualified for evaluation of effectiveness?

The 170 subjects had to be proven to be without evidence of infection up to seven days after Dose 2. If they became symptomatic later, they would either have an in-person or tele-health visit and get a nasal swab test done. If the swab tested positive and the subject had at least one symptom of COVID, he or she received a COVID-19 diagnosis. The incidence rate per 1,000 person-years would be calculated.

Phase 2/3 was anticipated to be 'event-driven', with the assumption of a true Vaccine Effectiveness (VE) rate of ≥60%, after the last dose of investigational product. Therefore, a target of 164 primary-endpoint cases of confirmed COVID-19 due to SARS-CoV-2 occurring at least seven days following the last dose of the primary series of the candidate vaccine would have been sufficient to provide 90% power to conclude true VE >30% with high probability. An unblinded statistical team planned to perform interim analysis for efficacy and futility after accrual of at least 32, 62, 92, 120 and with final analysis planned with accrual of 164 cases.

first primary endpoint and the futility boundary may be subject to change to reflect subsequent program-related decisions by the sponsor.

- Efficacy and futility boundaries will be applied in a nonbinding way.

Bayesian approaches require specification of a prior distribution for the possible values of the unknown vaccine effect, thereby accounting for uncertainty in its value. A minimally informative beta prior, beta (0.700102, 1), is proposed for $\theta = (1\text{-VE})/(2\text{-VE})$. The prior is centered at $\theta = 0.4118$ (VE=30%) which can be considered pessimistic. The prior allows considerable uncertainty; the 95% interval for θ is (0.005, 0.964) and the corresponding 95% interval for VE is (-26.2, 0.995).

Table 5 illustrates the boundary for efficacy and futility if IAs are performed after accrual of 32 62, 92, and 120 cases in participants without evidence of infection before vaccination.

Table 5. Interim Analysis Plan and Boundaries for Efficacy and Futility

Analysis	Number of Cases	Success Criteria[a]	Futility Boundary
		VE Point Estimate (Case Split)	VE Point Estimate (Case Split)
IA1	32	76.9% (6:26)	11.8% (15:17)
IA2	62	68.1% (15:47)	27.8% (26:36)
IA3	92	62.7% (25:67)	38.6% (35:57)
IA4	120	58.8% (35:85)	N/A
Final	164	52.3% (53:111)	

Abbreviations: IA = interim analysis; N/A = not applicable; VE = vaccine efficacy.
Note: Case split = vaccine : placebo.
a. Interim efficacy claim: P(VE >30%|data) > 0.995; success at the final analysis: P(VE >30%|data) > 0.986.

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, p. 1643.]

In the analysis sets in Protocol Amendment 5, the evaluable efficacy population was defined as seen in the figure below. Thereafter, it was implicitly printed throughout the protocol that the dosing interval chosen was 21 days between Dose 1 and Dose 2, with a window of allowance of 19 to 23 days after Dose 1. In the statistical analysis sets throughout the protocol documentation, a number was never assigned to the "predefined window." However, it should have read "as randomized

within the predefined window (within 19 to 23 days after Dose 1)," as there was evidence that a window had been defined.

9.3. Analysis Sets

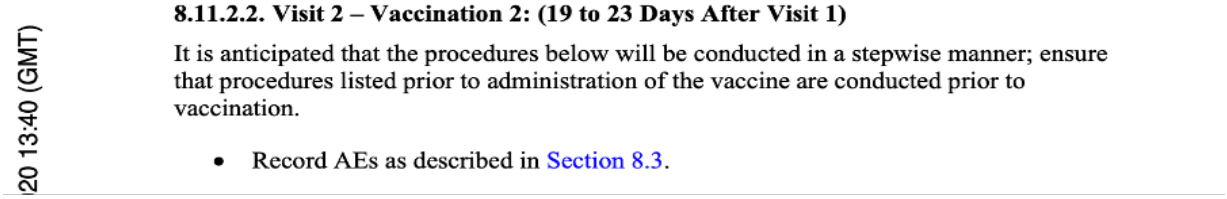
For purposes of analysis, the following populations are defined:

Population	Description
Enrolled	All participants who have a signed ICD.
Randomized	All participants who are assigned a randomization number in the IWR system.
Dose 1 evaluable immunogenicity	All eligible randomized participants who receive the vaccine to which they are randomly assigned at the first dose, have at least 1 valid and determinate immunogenicity result 21 days after Dose 1, have blood collection within an appropriate

Population	Description
	window after Dose 1, and have no other major protocol deviations as determined by the clinician.
Dose 2 evaluable immunogenicity	All eligible randomized participants who receive 2 doses of the vaccine to which they are randomly assigned, within the predefined window, have at least 1 valid and determinate immunogenicity result after Dose 2, have blood collection within an appropriate window after Dose 2, and have no other major protocol deviations as determined by the clinician.
Dose 1 all-available immunogenicity	All participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 1 but before Dose 2.
Dose 2 all-available immunogenicity	All participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable efficacy	All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have the efficacy measurement after the last dose of study intervention, and have no other major protocol deviations as determined by the clinician. A major protocol deviation will exclude a participant from the evaluable efficacy population from the date that it occurs through the participant's remaining follow-up.
All-available efficacy	All eligible randomized participants who receive at least 1 vaccination and have the efficacy measurement at any time after Dose 1. All eligible randomized participants who complete 2 vaccination doses and have the efficacy measurement at any time after Dose 2.
Safety	All randomized participants who receive at least 1 dose of the study intervention.

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, pp. 1633-1634.]

This was the last protocol change prior to the official start of Phase 3 of the trial. Subsequent protocol amendments dated 8 September 2020, 6 October 2020, 15 October 2020, and 29 October 2020 maintained the parameters outlined above as evidenced by the snapshots below from the protocol amendment dated 29 October 2020.



20 13:40 (GMT)

8.11.2.2. Visit 2 – Vaccination 2: (19 to 23 Days After Visit 1)

It is anticipated that the procedures below will be conducted in a stepwise manner; ensure that procedures listed prior to administration of the vaccine are conducted prior to vaccination.

- Record AEs as described in Section 8.3.

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, p. 1029.]

9.3. Analysis Sets

For purposes of analysis, the following populations are defined:

Population	Description
Enrolled	All participants who have a signed ICD.
Randomized	All participants who are assigned a randomization number in the IWR system.
Dose 1 evaluable immunogenicity	For Phase 1 only, all eligible randomized participants who receive the vaccine to which they are randomly assigned at the first dose, have at least 1 valid and determinate immunogenicity result after Dose 1, have blood collection within an appropriate window after Dose 1, and have no other important protocol deviations as determined by the clinician.
Dose 2 evaluable immunogenicity	All eligible randomized participants who receive 2 doses of the vaccine to which they are randomly assigned, within the predefined window, have at least 1 valid and determinate immunogenicity result after Dose 2, have blood collection within an appropriate window after Dose 2, and have no other important protocol deviations as determined by the clinician.

Population	Description
Dose 1 all-available immunogenicity	For Phase 1 only: all randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 1 but before Dose 2.
Dose 2 all-available immunogenicity	All randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable efficacy	All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window and have no other important protocol deviations as determined by the clinician.
All-available efficacy	1. All randomized participants who receive at least 1 vaccination. 2. All randomized participants who complete 2 vaccination doses.
Safety	All randomized participants who receive at least 1 dose of the study intervention.

9.4 Statistical Analyses

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, pp. 1042-1043.]

1.3.2. Phase 2/3

An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 convalescent visit are required at any time between Visit 1 (Vaccination 1) and Visit 6 (24-month follow-up visit) that potential COVID-19 symptoms are reported, including MIS-C.

Visit Number	1	2	3	4	5	6	Unplanned	Unplanned
Visit Description	Vaccination 1	Vaccination 2	1-Month Follow-up Visit	6-Month Follow-up Visit	12-Month Follow-up Visit	24-Month Follow-up Visit	Potential COVID-19 Illness Visit[a]	Potential COVID-19 Convalescent Visit
Visit Window (Days)	Day 1[b]	19 to 23 Days After Visit 1	28 to 35 Days After Visit 2	175 to 189 Days After Visit 2	350 to 378 Days After Visit 2	714 to 742 Days After Visit 2	Optimally Within 3 Days After Potential COVID-19 Illness Onset	28 to 35 Days After Potential COVID-19 Illness Visit
Obtain informed consent	X							
Assign participant number	X							
Obtain demography and medical history data	X							
Perform clinical assessment[c]	X							
For participants who are HIV-positive, record latest CD4 count and HIV viral load	X		X	X	X	X		
Measure height and weight	X							
Measure temperature (body)	X	X						
Perform urine pregnancy test (if appropriate)	X	X						
Confirm use of contraceptives (if appropriate)	X	X	X					
Collect nonstudy vaccine information	X	X	X	X				
Collect prohibited medication use		X	X	X	X	X	X	X
Confirm eligibility	X	X						
Review temporary delay criteria	X	X						
Collect blood sample for immunogenicity assessment[d]	~20 mL/ ~10 mL		~20 mL/ ~10 mL	~20 mL/ ~10 mL	~20 mL/ ~10 mL	~20 mL/ ~10 mL		~20 mL/ ~10 mL
Obtain nasal (midturbinate) swab	X	X					X	

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, p. 964.]

The data cut-off date was 14 November 2020, and another protocol amendment occurred on 1 December 2020 prior to issuance of the EUA. It did not outline any changes to the parameters.

Why give this long explanation into the many iterations of the protocol and have so much discussion about the 'predefined window'?

The FDA issued the EUA approving the Pfizer COVID-19 vaccine on 11 December 2020.

Table 6. Final Analysis of Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants Without Evidence of Prior SARS-CoV-2 Infection, Evaluable Efficacy Population

Pre-specified Age Group	BNT162b2 N[a] = 18198 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a] =18325 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)	Met Predefined Success Criterion*
All participants	8 2.214 (17411)	162 2.222 (17511)	95.0 (90.3, 97.6)[e]	Yes
16 to 55 years	5 1.234 (9897)	114 1.239 (9955)	95.6 (89.4, 98.6)[f]	NA
>55 years	3 0.980 (7500)	48 0.983 (7543)	93.7 (80.6, 98.8)[f]	NA

*Success criterion: the posterior probability that true vaccine efficacy > 30% conditioning on the available data is >99.5% at the final analysis

[a] N = number of participants in the specified group.

[b] n1 = Number of participants meeting the endpoint definition.

[c] Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

[d] n2 = Number of participants at risk for the endpoint.

[e] Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.

[f] Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

[*Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum Identifying Information.* https://www.fda.gov/media/144416/download, p. 18.]

The screenshot shown above is from the EUA Review Memorandum [*Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum Identifying Information. (n.d.).* https://www.fda.gov/media/144416/download], the Final Analysis of Efficacy against Confirmed COVID -19, that was the basis of the EUA.

These eight positive vaccinated and 162 positive placebo subjects are the '170 that changed the world'. Were they as kosher as they were meant to be? Remember, patients that are part of the evaluable population needed to have *zero* protocol deviations.

For the first time publicly, a number appeared after the words "predefined window." (See screenshot below.) It explicitly stated exclusions in the trial would include those who did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19 to 42 days after Dose 1).

groups. Of 43,448 participants in the Phase 2/3 all-enrolled population, 94.2% of vaccine recipients and 94.1% of placebo recipients completed 2 doses (data not shown).

Table 2. Efficacy Populations, Treatment Groups as Randomized

Population	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	21823 (100.0)	21828 (100.0)	43651 (100.0)
Dose 1 all-available efficacy population	21768 (99.7)	21783 (99.8)	43551 (99.8)
Participants without evidence of infection before Dose 1	20314 (93.1)	20296 (93.0)	40610 (93.0)
Participants excluded from Dose 1 all-available efficacy population	55 (0.3)	45 (0.2)	100 (0.2)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	54 (0.2)	45 (0.2)	99 (0.2)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Dose 2 all-available efficacy population	20566 (94.2)	20536 (94.1)	41102 (94.2)
Participants without evidence of infection prior to 7 days after Dose 2	18701 (85.7)	18627 (85.3)	37328 (85.5)
Participants without evidence of infection prior to 14 days after Dose 2	18678 (85.6)	18563 (85.0)	37241 (85.3)
Participants excluded from Dose 2 all-available efficacy population	1257 (5.8)	1292 (5.9)	2549 (5.8)
Reason for exclusion[c]			
Did not receive 2 vaccinations	1256 (5.8)	1292 (5.9)	2548 (5.8)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Evaluable efficacy (7 days) population	20033 (91.8)	20244 (92.7)	40277 (92.3)
Evaluable efficacy (14 days) population	20033 (91.8)	20243 (92.7)	40276 (92.3)
Participants excluded from evaluable efficacy (7 days) population	1790 (8.2)	1584 (7.3)	3374 (7.7)
Participants excluded from evaluable efficacy (14 days) population	1790 (8.2)	1585 (7.3)	3375 (7.7)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	36 (0.2)	26 (0.1)	62 (0.1)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	1550 (7.1)	1561 (7.2)	3111 (7.1)
Had other important protocol deviations on or prior to 7 days after Dose 2	311 (1.4)	60 (0.3)	371 (0.8)
Had other important protocol deviations on or prior to 14 days after Dose 2	311 (1.4)	61 (0.3)	372 (0.9)

[a] n = Number of participants with the specified characteristic.
[b] These values are the denominators for the percentage calculations.
[c] Participants may have been excluded for more than 1 reason.
Note: 100 participants 12 through 15 years of age with limited follow-up are included in the randomized population (49 in the vaccine group and 51 in the placebo group). Some of these subjects were included in the denominators of efficacy analyses, depending on the population analyzed, but did not contribute primary endpoint cases and do not affect efficacy conclusions for ages 16 years and above.

[*Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum Identifying Information*, https://www.fda.gov/media/144416/download, p. 18.]

As a result, the following questions are imperative:

- Why, in the first trial of a new drug, would a doubling of the dosing interval that was so painstakingly set earlier be accepted?
- Is this a protocol violation?
- The protocol described a 19- to 23-day variance of the 21-day dose, as was stated across multiple iterations of the protocol.
    - Should someone who got vaccinated on day 18 instead of day 19 be accepted?
    - Why should someone vaccinated on day 41, a bigger deviation of days, be accepted?
- How does this bigger dosing variation in dosing schedules affect the efficacy of the drug?

The data simply are not available. Therefore, subsequent studies looking at different dosing intervals individually would be needed. Such a practice would normally constitute a protocol violation, including patients removed from the evaluable population, unless a formal protocol amendment had been filed. The time to file this amendment would also be prior to starting the trial. However, based on the released and publicly available documents, no such protocol amendment exists.

These 170 patients were not easy to find, so how did the authors go about finding them?

On March 1, 2022, a 671-page Pfizer document (*25742_S1_M5_5351_c4591001-fa-interim-lab-measurements.pdf*, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-lab-measurements.pdf) was released by the FDA. Starting on page 586, we began to find our elusive subjects who would have qualified for the interim analysis. A separate document released publicly on the same date (*125742_S1_M5_5351_c4591001-fa-interim-lab-measurements-sensitive.pdf*, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-fa-interim-lab-measurements-sensitive.pdf) listed the subjects, starting on page 66, who would also qualify to be part of the *evaluable efficacy population*. Reconciling the two, we were able to find the subjects who became part of the *Final Analysis of Efficacy*. [https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/070122/125742_S1_M5_5351_c4591001-fa-interim-narrative-sensitive.pdf, pp. 1059-2506.]

Taking another approach, we also cross-checked the list we compiled against published demographic data available in a *New England Journal of Medicine* article published on 10 Dec 2020. [Polack, F.P., Thomas, S.J., Kitchin, N., et.al. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *New England Journal of Medicine*, 383(27). doi:10.1056/nejmoa2034577, https://www.nejm.org/doi/full/10.1056/NEJMoa2034577.]

This table demonstrates our findings:

170 Efficacy Population Analysis

- End-Point alignment match with published tables

Category	BNT162b2	Placebo	Total
	8	162	170
16 to 55	5	114	119
>55 yr	3	48	51
>=65 yr	1	19	20
>=75 yr	0	5	5
Male	3	81	84
Female	5	81	86
White	7	146	
Black	0	7	
Others	1	9	
Hispanic	3	53	
Non-Hispanic	5	109	
Argentina	1	35	36
Brazil	1	8	9
USA	6	119	125
	8	162	170

SAFETY AND EFFICACY OF THE BNT162b2 VACCINE

Table 3. Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection before 7 Days after Dose 2.

Efficacy End-Point Subgroup	BNT162b2 (N=18,198) No. of Cases	BNT162b2 (N=18,198) Surveillance Time (No. at Risk)*	Placebo (N=18,325) No. of Cases	Placebo (N=18,325) Surveillance Time (No. at Risk)*	Vaccine Efficacy, % (95% CI)†
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.0–97.9)
Age group					
16 to 55 yr	5	1.234 (9,897)	114	1.239 (9,955)	95.6 (89.4–98.6)
>55 yr	3	0.980 (7,500)	48	0.983 (7,543)	93.7 (80.6–98.8)
≥65 yr	1	0.508 (3,848)	19	0.511 (3,880)	94.7 (66.7–99.9)
≥75 yr	0	0.102 (774)	5	0.106 (785)	100.0 (−13.1–100.0)
Sex					
Male	3	1.124 (8,875)	81	1.108 (8,762)	96.4 (88.9–99.3)
Female	5	1.090 (8,536)	81	1.114 (8,749)	93.7 (84.7–98.0)
Race or ethnic group‡					
White	7	1.889 (14,504)	146	1.903 (14,670)	95.2 (89.8–98.1)
Black or African American	0	0.165 (1,502)	7	0.164 (1,486)	100.0 (31.2–100.0)
All others	1	0.160 (1,405)	9	0.155 (1,355)	89.3 (22.6–99.8)
Hispanic or Latinx	3	0.605 (4,764)	53	0.600 (4,746)	94.4 (82.7–98.9)
Non-Hispanic, non-Latinx	5	1.596 (12,548)	109	1.608 (12,661)	95.4 (88.9–98.5)
Country					
Argentina	1	0.351 (2,545)	35	0.346 (2,521)	97.2 (83.3–99.9)
Brazil	1	0.119 (1,129)	8	0.117 (1,121)	87.7 (8.1–99.7)
United States	6	1.732 (13,359)	119	1.747 (13,506)	94.9 (88.6–98.2)

* Surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from 7 days after the second dose to the end of the surveillance period.
† The confidence interval (CI) for vaccine efficacy is derived according to the Clopper–Pearson method, adjusted for surveillance time.
‡ Race or ethnic group was reported by the participants. "All others" included the following categories: American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported.

BNT162b2	Placebo	Total	
1	4	5	Asian
0	2	2	Not Reported
0	1	1	American Indian or Alaska Native
0	1	1	Native Hawaiian or Other Pacific Islander
0	1	1	Multiple
1	9	10	

170 Efficacy Population Analysis (cont.)

- End-Point alignment match with published tables

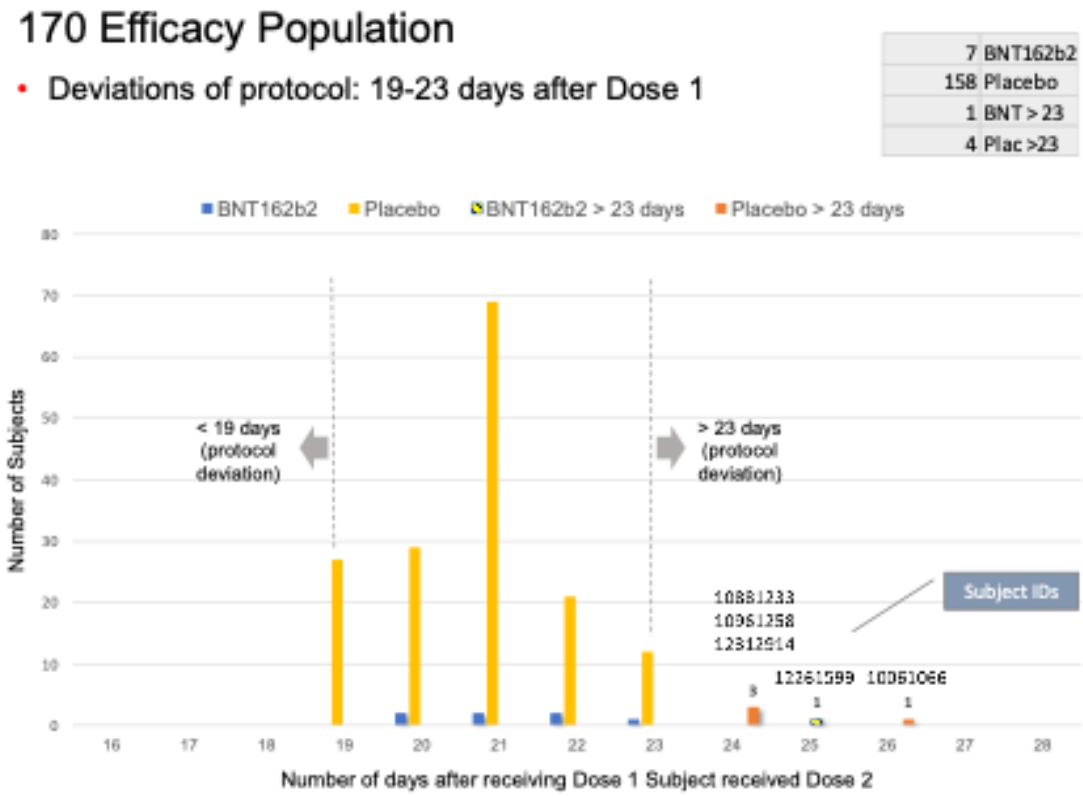
Obese	BNT162b2	Placebo	Total
Yes	3	67	70
No	5	95	100
	8	162	170
Age group (years) and obese			
16-64 not obese	4	83	
16-64 and obese	3	60	
>=65 not obese	1	12	
>=65 and obese	0	7	

Efficacy Endpoint Subgroup	n1[b]	BNT162b2 (30 µg) (N=18198) Surveillance Time[c] (n2[d])	n1[b]	Placebo (N=18325) Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
At risk[f]						
Yes	4	1.025 (8030)	86	1.025 (8029)	95.3	(87.7, 98.8)
No	4	1.189 (9381)	76	1.197 (9482)	94.7	(85.9, 98.6)
Age group (years) and at risk						
16–64 and not at risk	4	0.962 (7671)	69	0.964 (7701)	94.2	(84.4, 98.5)
16–64 and at risk	3	0.744 (5878)	74	0.746 (5917)	95.9	(87.6, 99.2)
≥65 and not at risk	0	0.227 (1701)	7	0.233 (1771)	100.0	(29.0, 100.0)
≥65 and at risk	1	0.281 (2147)	12	0.279 (2109)	91.7	(44.2, 99.8)
Obese[g]						
Yes	3	0.763 (6000)	67	0.782 (6103)	95.4	(86.0, 99.1)
No	5	1.451 (11406)	95	1.439 (11404)	94.8	(87.4, 98.3)
Age group (years) and obese						
16–64 and not obese	4	1.107 (8811)	83	1.101 (8825)	95.2	(87.3, 98.7)
16–64 and obese	3	0.598 (4734)	60	0.609 (4789)	94.9	(84.4, 99.0)
≥65 and not obese	1	0.343 (2582)	12	0.338 (2567)	91.8	(44.5, 99.8)
≥65 and obese	0	0.165 (1265)	7	0.173 (1313)	100.0	(27.1, 100.0)

Table S4 | Vaccine Efficacy from 7 Days after Dose 2 by Underlying Comorbidities among Participants without Evidence of Infection Prior to 7 Days after Dose 2. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period. a. N = number of participants in the specified group. b. n1 = Number of participants meeting the endpoint definition. c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period. d. n2 = Number of participants at risk for the endpoint. e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time. f. At risk is defined as having at least one of the Charlson Comorbidity Index categories or obesity (body mass index [BMI] ≥30 kg/m^2). g. Obese is defined as BMI ≥30 kg/m^2.

10

The distribution of subjects' timing of the second vaccine dose:



What did the analysis of the 170 subjects show?

We found five subjects whose dosing interval between Dose 1 and Dose 2 fell outside the 19- to 23-day window.

1. C4591001 1006 10061066 (26-day interval), placebo
2. C4591001 1088 10881233 (24-day interval), placebo
3. C4591001 1096 10961258 (24-day interval), placebo
4. C4591001 1226 12261599 (25-day interval), vaccine
5. C4591001 1231 12312914 (24-day interval), placebo

KEY

C4591001	1000-4444	8-digit number 1000 – x
Pfizer Trial	Site ID	Subject ID by Site

Whilst we understand the temptation of clinical trial specialists to include these subjects in the Final Analysis of Efficacy, this is *not* how clinical trials are conducted. An important part of any clinical trial is the removal of subjects who did not follow the trial protocol from analysis. If a deviation in the protocol is to be included, an appropriate amendment must be filed.

Why, then, is the extension of the dosing interval to 42 days so important?

We were intrigued by such a widening of the dosing interval, and further conducted a brief analysis of all the participants enrolled into the trial. When one looks at the Excel table below, he can see that the trial cutoff date for consideration of the EUA was 14 November 2020. Hence, nobody who received Dose 2 on 8 November 2020 and after could be part of the evaluable population for efficacy, as Dose 2 plus seven days would be after 14 November 2020. From the enrolled population, after elimination of a) those who did not receive their two doses and b) those whose dosing interval fell below 19 days and after 42 days, we can compare how many patients could be recoverable if the "predefined window" was 19-42 days versus 19-23 days. The undocumented change in the protocol (i.e., without an amendment) enabled Pfizer to include an additional 1,410 subjects in the analysis, because – by adding 19 days – Pfizer was able to recover 1,410 patients who were otherwise ineligible for the efficacy analysis. Those 1,410 enabled the inclusion of the four placebo patients and one BNT162b2 patient in the 170 population. (See chart below.)

Protocol 19-23 days:	Enrolled	No Dose	Dose 1	Delta	Dose 2	<8 Nov	< 19 Days	> 23 + 7	> 14 Nov 2020 Deviations		Eligible
BNT162b2	21,774	54	21633	1,117	20516	19439	171	775	1,077	2,023	17,416
Placebo	21,777	45	21676	1,188	20488	19443	174	806	1,045	2,025	17,418
Total	43,551	99	43,309	**2,305**	41,004	38,882	345	1,581	2,122	**4,048**	**34,834**
Protocol 19-42 days:	**Enrolled**	**No Dose**	**Dose 1**	**Delta**	**Dose 2**	**<8 Nov**	**< 19 Days**	**> 42 + 7**	**> 14 Nov 2020 Deviations**		**Eligible**
BNT162b2	21,774	54	21633	1,117	20516	19,439	171	96	1077	1,344	18,095
Placebo	21,777	45	21676	1,188	20488	19443	174	75	1,045	1,294	18,149
Total	43,551	99	43,309	**2,305**	41,004	38,882	345	171	2,122	**2,638**	**36,244**
Recapture								**1,410**	**0**	**1,410**	**-1,410**

The 170 patients came only from 66 of the 153 sites, even though all patients enrolled in the trial should have been eligible to be included in the Final Efficacy Analysis. As a team, we intend to audit the sites that enrolled patients in this trial.

Questions continue to arise. After this deep dive, we still have concerns about some of the other subjects that demand answers.

Patients in the 170 who had other major protocol deviations:

- Subject C4591001 10681082, completed the protocol and received his or her second dose on 21 September 2020, became symptomatic on 1 November 2020 and tested positive on 2 November 2020. However, this patient is listed as having a *protocol deviation* of Dosing Administration Error (subject possibly did not receive correct dose of the vaccine). This was already known according to documents dated 30 November 2020 and reinforced again in documents dated 1 April 2021. *This subject should not be part of any efficacy analysis.* We have cross-checked the errata documentation in case an error of documentation had occurred and could not find it pertaining to this subject.

- Subject C4591001 12313895 received his or her second dose of the vaccine on 13 September 2020. The patient developed COVID symptoms on 3 October 2020 and had a positive swab, making him or her one of the patients in the evaluable efficacy population. However, this patient is found on a list dated 30 November 2020, having important *protocol deviations*, having received blood or plasma products within 60 days of enrollment through conclusion of the study. *This subject should not be part of any analysis of efficacy*. We also cross-checked this subject with the errata document.

Other issues uncovered in our 170 Final Efficacy Analysis:

- Subject C4591001 44441224 received his or her second dose on 13 October 2020 and had first symptoms present on 25 October 2020. The subject had a positive swab, which was included in the data analysis. But he or she requested withdrawal from the trial on 12 November 2020. This *raises ethical questions about using their data in a study*.

- Subject C4591001 10161004 received his or her second dose on 19 August 2020, developed fever, new loss of taste or smell, muscle pain and a sore throat on 21 August 2020. A nasal swab, collected on 8 September 2020 for the illness episode of 21 August 2020, was negative. The patient re-presented again on 17 October 2020 with a new loss of taste or smell and sore throat, and this time the COVID swab was positive, and the patient was included in the evaluable population. This highlights the tenuous nature of COVID diagnosis.

- Subject C4591001 10921130, received his or her second dose on 22 September 2020, presented with COVID illness on 12 October 2020 and tested positive. Intriguingly, the patient is also *found on the list of patients withdrawn from the trial* for achieving the endpoint of the trial.

- Subject C4591001 11681007 received his or her second dose on 1 September 2020, had one illness visit on 7 October 2020, had a swab dated 6 October 2020 that was negative, and another swab on 8 October 2020 that was positive.

- We also noted interesting coincidences of these 170 in a trial of nearly 44,000 enrolled subjects and an evaluable group of around 37,000, where every patient had equal chances of reaching the evaluable analysis. There were six paired instances of sequential numbers.

Study ID	Site	Subject ID
C4591001	1016	10161003
C4591001	1016	10161004
C4591001	1123	11231255
C4591001	1123	11231256
C4591001	1141	11411161
C4591001	1141	11411162
C4591001	1168	11681007
C4591001	1168	11681008
C4591001	1231	12315636
C4591001	1231	12315637
C4591001	1241	12412017
C4591001	1241	12412018

However, going back to the 'predefined window' issue, when did the doubling of a dosing interval of a novel drug seemingly become an acceptable practice?

The Statistical Analysis Plan (SAP) for Phase 1 of this study was finalized on 18 November 2020 and approved on 27 November 2020, chronologically *after* the Phase 1/2/3 SAP of this study, which was finalized on the 2 November 2020, showing that Pfizer disregarded chronological order. [https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-fa-interim-sap.pdf]

This plan, as described before in the Clinical Protocol, described a study design of a two-dose schedule separated by 21 days. (See below.)

2.2. Study Design

2.2.1. Overall Design

This is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate–selection, and efficacy study in healthy individuals.

The study consists of 2 parts. Phase 1: to identify preferred vaccine candidate(s) and dose level(s); Phase 2/3: an expanded cohort and efficacy part. These parts, and the progression between them, are detailed in the schema (see protocol, Section 1.2).

The study will evaluate the safety, tolerability, and immunogenicity of 2 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the efficacy of 1 candidate:

- As a 2-dose (separated by 21 days) schedule;
- At various different dose levels in Phase 1;
- In 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55, or >55 years of age]).

Dependent upon safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany (BNT162-01), it is possible that groups in Phase 1 may be started at the next highest dose, groups may not be started, groups may be terminated early, and/or groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses.

The study is observer-blinded, as the physical appearance of the investigational vaccine candidates and the placebo may differ. The participant, investigator, study coordinator, and other site staff will be blinded. At the study site, only the dispenser(s)/administrator(s) are unblinded.

To facilitate rapid review of data in real time, sponsor staff will be unblinded to vaccine

[https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-fa-interim-sap.pdf – page 11.]

However, for the first time found in the Analysis sets, the predefined window had a number assigned to it…

4. ANALYSIS SETS (POPULATIONS FOR ANALYSIS)

Data for all participants will be assessed to determine if participants meet the criteria for inclusion in each analysis population prior to unblinding and releasing the database and classifications will be documented per SOPs.

Population	Description
Enrolled	All participants who have a signed ICD.
Randomized	All participants who are assigned a randomization number in the IWR system.
Dose 1 evaluable immunogenicity	For Phase 1 only, all eligible randomized participants who receive the vaccine to which they are randomly assigned at the first dose, have at least 1 valid and determinate immunogenicity result from the blood collection within an appropriate window after Dose 1 (same as visit window, ie, within 19-23 days after Dose 1), and have no other important protocol deviations as determined by the clinician.
Dose 2 evaluable immunogenicity	All eligible randomized participants who receive 2 doses of the vaccine to which they are randomly assigned, with Dose 2 received within the predefined window (within 19-42 days after Dose 1), have at least 1 valid and determinate immunogenicity result after Dose 2 from the blood collection within an appropriate window after Dose 2 (within 6-8 days after Dose 2 for Phase 1 and within 28-42 days after Dose 2 for Phase 2/3), and have no other important protocol deviations as determined by the clinician.
Dose 1 all-available immunogenicity	For Phase 1 only: all randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 1 but before Dose 2.
Dose 2 all-available immunogenicity	All randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable efficacy (7 days)	All eligible randomized participants who receive all vaccination(s) as randomized, with Dose 2 received within the predefined window (within 19-42 days after Dose 1) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2.

[https://www.phmpt.org/wp-content/uploads/2022/07/125742_S1_M5_5351_c4591001-fa-interim-sap.pdf, p. 25.]

Conclusions

We are now in an intriguing situation where the endpoint for immunogenicity data for Phase 1, has a visit window of 19 to 23 days; but for Phase 2, for the same immunogenicity data of the same drug, the window was 19 to 42 days. They had not met the threshold for final interim analysis within the 19- to 23-day window but managed to meet it by changing the threshold.

This highlights questions of when the data lock happened, and if the "predefined window" is in fact a post-hoc defined window. Questions arise as to why ambiguity was allowed with regards to the words "predefined window" throughout the trial, in which a number was not defined in all the analysis sets.

We identified that seven patients – five outside of the dosing window and two with major protocol deviations – were part of the final efficacy analysis; therefore, the basis on which the EUA was granted must be revisited, as *this brings the evaluable population down to 163, which is below the final threshold for interim analysis*. So many norms in society have fallen during the pandemic. If the scientific community is to move forward with integrity, it cannot allow practices like this to stand.

As a team of volunteers, we continue our audit of all the sites with publicly available information.

An extraordinary amount of taxpayer money was used for the Pfizer trial whose Primary Investigators (PIs) may have not followed the trial protocol correctly. In normal circumstances, clinical trials are funded by the company running the trial from their research budget. What we have found in these documents calls into question the validity of the clinical trial results, as well as the potential misuse of billions of United States taxpayer dollars.

Excel: 170 Efficacy Population Analysis 19-23 days protocol deviation (chart) 26 Sep 2022 (https://dailyclout.io/wp-content/uploads/170-Efficacy-Population-Analysis-19-23-days-protocol-deviaition-chart-26-Sep-2022-Final.xlsx)

Report 39: "Twenty-Two Cases of Rare Myocarditis by February 2021, Yet Pfizer Said No "New Safety Issues." FDA Waits Until June 25, 2021, to Include Myocarditis Risk in Fact Sheets." by a Team 1 physician (Edited by Chris Flowers, MD, and Amy Kelly) – Team 1.

As initially reported by Chris Flowers, M.D., on DailyClout.io in April 2022, myocarditis – inflammation of the heart muscle (a.k.a., myocardium) that can reduce the heart's ability to pump blood as well as cause chest pain, shortness of breath, and rapid or irregular heart rhythms (a.k.a., arrhythmias) [https://www.mayoclinic.org/diseases-conditions/myocarditis/symptoms-causes/syc-20352539] – is a serious adverse event (SAE) that the Food and Drug Administration (FDA) knew about in May 2021 when it renewed the Emergency Use Authorization (EUA) for Pfizer's mRNA COVID-19 vaccine, BNT162b2. [https://dailyclout.io/pfizer-vaccine-fda-fails-to-mention-risk-of-heart-damage-in-teens/] This report brings to light additional information on myocarditis from Pfizer's "5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162b2) Received Through 28-Feb-2021." [https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf]

As early as February 2021, Pfizer had 22 cases of myocarditis, less than three months into the mRNA COVID-19 mass vaccination program in the United States. In fact, the FDA did have this information when 5.3.6. was given to them by Pfizer on April 30, 2021.

These cases had onset within seven days, with a median onset of two days, and Pfizer concluded that there were no "new safety issues." [https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf and https://my.clevelandclinic.org/health/diseases/22129-myocarditis] *Speaking as a physician, this early post-authorization data, in and of itself, warns of the "increased risks of myocarditis," "particularly within 7 days," as today is warned in the COMIRNATY® package insert*. [https://labeling.pfizer.com/ShowLabeling.aspx?id=15623&format=pdf]

Reviewing the reissue of Pfizer's "5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162b2) Received Through 28-Feb-2021" (received by the FDA on April 30, 2021, and then published by the FDA on April 1, 2022, with original FDA publication on November 17, 2021), this physician was struck by the high number of rare adverse events (AEs) in Table 7 – e.g., myocarditis:

- In fewer than three months of post-authorization reporting (mid-December 2020 through February 28, 2021).
- With an Adverse Event of Special Interest (AESI) category *median relevant event onset latency* of less than 24 hours.
- With a conclusion of no new safety issues [https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf].

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
Immune-Mediated/Autoimmune AESIs *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity*	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[1]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

Figure 1: From p. 20 of "5.3.6 Cumulative Analysis of Postmarketing Adverse Event Reports"

Without seeing the Individual Case Safety Reports (ICSRs) that made up the pooled data in Table 7, could anyone, outside of Pfizer, suspect a *new safety issue* on his or her own?

Pfizer had to report all post-authorization SAEs to the Vaccine Adverse Reporting System (VAERS), so now the public can see actual, *vetted* ICSR data held, as of February 28, 2021, and come up with their own conclusion.

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event;
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in children and adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

[https://nps.edu/documents/111291366/124403968/Pfizer-BioNTech+COVID-19+Vaccine+EUA+LOA+%2811+Dec+2020%29.pdf/106e9662-956c-aa94-8d4b-a945a6a10b87?t=1608071313236, p. 6.]

Based on a VAERS query, one can view the SAEs received by Pfizer:

- Through February 28, 2021
- For the Preferred Term (PT) myocarditis (Symptoms)

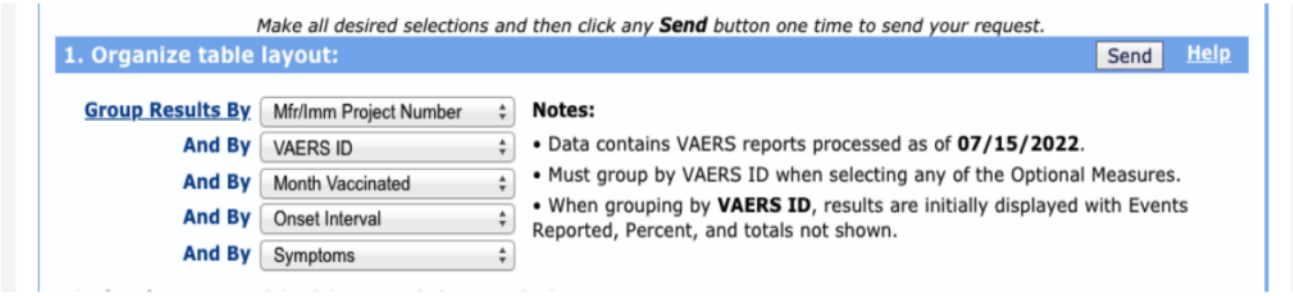


Figure 2: Screenshot of VAERS search criteria used on 7/15/2022.

[https://wonder.cdc.gov/vaers.html]

This shows that 22 cases of myocarditis were received by Pfizer (have an Mfr/Imm Project Number) through February 28, 2021, and assessed by its medical review team prior to submitting to VAERS:

- In fewer than three months of post-authorization reporting, Pfizer had twenty-two (22) reports of a rare condition, PT: myocarditis.
- Removing the six Pfizer reports with an *unknown onset interval*, the median (0000011222334557) *event onset latency* was two days – i.e., two days post-vaccination.

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 40 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.

Some measures are hidden, use Quick or More Options above to restore them.

Mfr/Imm Project Number	VAERS ID	Month Vaccinated	Onset Interval	Symptoms
ATPFIZER INC2021118627	1038875-1	Jan., 2021	Unknown	MYOCARDITIS
ATPFIZER INC2021164871	1048221-1	Jan., 2021	3 days	MYOCARDITIS
DEPFIZER INC2021113720	1037339-1	Jan., 2021	2 days	MYOCARDITIS
DEPFIZER INC2021127073	1047854-1	Jan., 2021	5 days	MYOCARDITIS
DEPFIZER INC2021164726	1048257-1	Feb., 2021	0 days	MYOCARDITIS
ESPFIZER INC2021069537	1010284-1	Jan., 2021	4 days	MYOCARDITIS
FIPFIZER INC2021074191	1014936-1	Jan., 2021	7 days	MYOCARDITIS
FRPFIZER INC2021146752	1050575-1	Jan., 2021	0 days	MYOCARDITIS
GBPFIZER INC2021024813	0961992-1	Unknown Date	Unknown	MYOCARDITIS
GBPFIZER INC2021024828	0960074-1	Unknown Date	Unknown	MYOCARDITIS
GBPFIZER INC2021024877	0960205-1	Jan., 2021	5 days	MYOCARDITIS
GBPFIZER INC2021033178	0984259-1	Jan., 2021	2 days	MYOCARDITIS
GBPFIZER INC2021076972	1014995-1	Jan., 2021	1 day	MYOCARDITIS
ILPFIZER INC2021123239	1035359-1	Unknown Date	Unknown	MYOCARDITIS
ILPFIZER INC2021123240	1039741-1	Unknown Date	Unknown	MYOCARDITIS
ILPFIZER INC2021170222	1048413-1	Jan., 2021	Unknown	MYOCARDITIS
ITPFIZER INC2021126263	1039803-1	Jan., 2021	1 day	MYOCARDITIS
ITPFIZER INC2021158572	1056330-1	Jan., 2021	0 days	MYOCARDITIS
NONE	0935452-1	Jan., 2021	0 days	MYOCARDITIS
NONE	0937932-1	Jan., 2021	1 day	MYOCARDITIS
NONE	0952497-1	Dec., 2020	15-30 days	MYOCARDITIS
NONE	0966243-1	Jan., 2021	3 days	MYOCARDITIS
NONE	0967286-1	Jan., 2021	3 days	MYOCARDITIS
NONE	0970198-1	Jan., 2021	1 day	MYOCARDITIS
NONE	0985024-1	Jan., 2021	2 days	MYOCARDITIS
NONE	0998532-1	Jan., 2021	1 day	MYOCARDITIS
NONE	1005747-1	Dec., 2020	15-30 days	MYOCARDITIS
NONE	1007452-1	Jan., 2021	0 days	MYOCARDITIS
NONE	1011883-1	Jan., 2021	4 days	MYOCARDITIS
NONE	1027010-1	Jan., 2021	8 days	MYOCARDITIS
NONE	1040340-1	Feb., 2021	0 days	MYOCARDITIS
NONE	1044420-1	Jan., 2021	15-30 days	MYOCARDITIS
NONE	1051710-1	Feb., 2021	10-14 days	MYOCARDITIS
NONE	1058476-1	Feb., 2021	0 days	MYOCARDITIS
NONE	1059800-1	Feb., 2021	3 days	MYOCARDITIS
NONE	1060751-1	Feb., 2021	3 days	MYOCARDITIS
PTPFIZER INC2021141150	1050958-1	Jan., 2021	2 days	MYOCARDITIS
PTPFIZER INC2021150774	1053553-1	Jan., 2021	3 days	MYOCARDITIS
SEPFIZER INC2021095017	1031453-1	Jan., 2021	0 days	MYOCARDITIS
USPFIZER INC2021129982	1048204-1	Jan., 2021	0 days	MYOCARDITIS

Figure 3: VAERS reports of myocarditis, received by Pfizer, through 2/28/2021.

Today, COMIRNATY® carries a warning regarding myocarditis and pericarditis.

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases

Figure 4: COMIRNATY's label warning about myocarditis and pericarditis.

[https://labeling.pfizer.com/ShowLabeling.aspx?id=15623&format=pdf]

Editing the VAERS query from *Month Vaccinated* to *Vaccine Dose*, and setting aside all unknowns, shows that four myocarditis cases occurred within seven days following the first dose and eight cases within seven days following the second dose.

Some measures are hidden, use Quick or More Options above to restore them.

Mfr/Imm Project Number	VAERS ID	Vaccine Dose	Onset Interval	Symptoms
ATPFIZER INC2021118627	1038875-1	1 Dose	Unknown	MYOCARDITIS
ATPFIZER INC2021164871	1048221-1	Unknown	3 days	MYOCARDITIS
DEPFIZER INC2021113720	1037339-1	2 Doses	2 days	MYOCARDITIS
DEPFIZER INC2021127073	1047854-1	2 Doses	5 days	MYOCARDITIS
DEPFIZER INC2021164726	1048257-1	2 Doses	0 days	MYOCARDITIS
ESPFIZER INC2021069537	1010284-1	1 Dose	4 days	MYOCARDITIS
FIPFIZER INC2021074191	1014936-1	Unknown	7 days	MYOCARDITIS
FRPFIZER INC2021146752	1050575-1	1 Dose	0 days	MYOCARDITIS
GBPFIZER INC2021024813	0961992-1	1 Dose	Unknown	MYOCARDITIS
GBPFIZER INC2021024828	0960074-1	Unknown	Unknown	MYOCARDITIS
GBPFIZER INC2021024877	0960205-1	2 Doses	5 days	MYOCARDITIS
GBPFIZER INC2021033178	0984259-1	Unknown	2 days	MYOCARDITIS
GBPFIZER INC2021076972	1014995-1	2 Doses	1 day	MYOCARDITIS
ILPFIZER INC2021123239	1035359-1	Unknown	Unknown	MYOCARDITIS
ILPFIZER INC2021123240	1039741-1	Unknown	Unknown	MYOCARDITIS
ILPFIZER INC2021170222	1048413-1	2 Doses	Unknown	MYOCARDITIS
ITPFIZER INC2021126263	1039803-1	1 Dose	1 day	MYOCARDITIS
ITPFIZER INC2021158572	1056330-1	2 Doses	0 days	MYOCARDITIS
NONE	0935452-1	2 Doses	0 days	MYOCARDITIS
NONE	0937932-1	Unknown	1 day	MYOCARDITIS
NONE	0952497-1	1 Dose	15-30 days	MYOCARDITIS
NONE	0966243-1	2 Doses	3 days	MYOCARDITIS
NONE	0967286-1	2 Doses	3 days	MYOCARDITIS
NONE	0970198-1	1 Dose	1 day	MYOCARDITIS
NONE	0970198-1	2 Doses	1 day	MYOCARDITIS
NONE	0985024-1	2 Doses	2 days	MYOCARDITIS
NONE	0998532-1	2 Doses	1 day	MYOCARDITIS
NONE	1005747-1	Unknown	15-30 days	MYOCARDITIS
NONE	1007452-1	2 Doses	0 days	MYOCARDITIS
NONE	1011883-1	2 Doses	4 days	MYOCARDITIS
NONE	1027010-1	Unknown	8 days	MYOCARDITIS
NONE	1040340-1	1 Dose	0 days	MYOCARDITIS
NONE	1044420-1	2 Doses	15-30 days	MYOCARDITIS
NONE	1051710-1	1 Dose	10-14 days	MYOCARDITIS
NONE	1058476-1	2 Doses	0 days	MYOCARDITIS
NONE	1059800-1	2 Doses	3 days	MYOCARDITIS
NONE	1060751-1	2 Doses	3 days	MYOCARDITIS
PTPFIZER INC2021141150	1050958-1	2 Doses	2 days	MYOCARDITIS
PTPFIZER INC2021150774	1053553-1	2 Doses	3 days	MYOCARDITIS
SEPFIZER INC2021095017	1031453-1	Unknown	0 days	MYOCARDITIS
USPFIZER INC2021129982	1048204-1	1 Dose	0 days	MYOCARDITIS

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Figure 5: VAERS query of myocarditis based on vaccine dose.

And, in people under 40 years of age, one finds there were five cases received by Pfizer, at least three with onset within seven days following the second dose:

Some measures are hidden, use Quick or More Options above to restore them.

Mfr/Imm Project Number	VAERS ID	Vaccine Dose	Onset Interval	Symptoms
ATPFIZER INC2021118627	1038875-1	1 Dose	Unknown	MYOCARDITIS
DEPFIZER INC2021113720	1037339-1	2 Doses	2 days	MYOCARDITIS
DEPFIZER INC2021164726	1048257-1	2 Doses	0 days	MYOCARDITIS
GBPFIZER INC2021033178	0984259-1	Unknown	2 days	MYOCARDITIS
ITPFIZER INC2021158572	1056330-1	2 Doses	0 days	MYOCARDITIS

Figure 6: VAERS reports of myocarditis, received by Pfizer, in people under 40 through 2/28/2021.

Lastly, two of the Pfizer reports have a written *causality* assessment by the medical reviewer. Even though all spontaneous reports have *implied causality* for regulatory reporting purposes, meaning the adverse event (AE) is suspected to be due to the suspect drug or biological product, many companies provide the medical reviewer's assessment of causality in the report narrative. [https://www.fda.gov/media/73593/download]

Below are details on the two reports, each acknowledging the temporal (i.e., time) relationship between the myocarditis event and the vaccine being given:

Mfr/Imm Project Number	**VAERS ID**	**Date Vaccinated**	**Date of Onset**	**Patient Age/Sex**	**Dose #**	**Excerpt from Medical reviewer assessment**
FRPFIZER INC2021146 752	105057 5-1	2021-01-14	2021-01-14	53/male	1	Based on the information currently available, a possible contributory role of the suspect drug in the reported event Myocarditis cannot be completely excluded given the known suspect drug profile and/or **impli ed temporal association**.
GBPFIZER INC2021024 877	096020 5-1	2021-01-04	2021-01-09	56/female	2	Based on the current available information and the **plausible drug-event temporal association**,

						a possible contributory role of the suspect product BNT162B2 to the development of event Myopericarditis cannot be totally excluded.

How can anyone who has reviewed the 22 myocarditis ICSRs, with all known onsets within seven days post-vaccination, agree with Pfizer's published conclusion, received by the FDA on April 30, 2021, of no *new safety issues*?

Prior to the FDA's initial myocarditis warning on June 25, 2021, Pfizer had received (at least through May 2021), 288 additional reports of myocarditis particularly within seven days. [https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021]

Messages:

- The full results are too long to be displayed, only non-zero rows are available.
- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 288 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.

Some measures are hidden, use Quick or More Options above to restore them.

Mfr/Imm Project Number	VAERS ID	Month Vaccinated	Onset Interval	Symptoms
BEPFIZER INC2021493485	1322699-1	Apr., 2021	2 days	MYOCARDITIS
BEPFIZER INC2021512236	1336372-1	Apr., 2021	2 days	MYOCARDITIS
CAPFIZER INC2021338214	1192743-1	Mar., 2021	0 days	MYOCARDITIS
CZPFIZER INC2021272166	1114000-1	Feb., 2021	2 days	MYOCARDITIS
DEPFIZER INC2021113725	1110755-1	Jan., 2021	1 day	MYOCARDITIS
DEPFIZER INC2021160575	1064494-1	Feb., 2021	0 days	MYOCARDITIS
DEPFIZER INC2021180660	1069358-1	Jan., 2021	2 days	MYOCARDITIS
DEPFIZER INC2021191556	1075474-1	Feb., 2021	3 days	MYOCARDITIS
DEPFIZER INC2021265061	1133102-1	Jan., 2021	5 days	MYOCARDITIS
DEPFIZER INC2021283010	1149564-1	Feb., 2021	0 days	MYOCARDITIS
DEPFIZER INC2021302339	1161296-1	Feb., 2021	3 days	MYOCARDITIS
DEPFIZER INC2021462194	1304024-1	Jan., 2021	5 days	MYOCARDITIS
DEPFIZER INC2021496575	1304022-1	Mar., 2021	4 days	MYOCARDITIS
DEPFIZER INC2021497309	1316459-1	Apr., 2021	3 days	MYOCARDITIS
DEPFIZER INC2021501452	1329809-1	Apr., 2021	2 days	MYOCARDITIS
DEPFIZER INC2021501462	1327867-1	Jan., 2021	0 days	MYOCARDITIS
DEPFIZER INC2021501471	1329811-1	Feb., 2021	2 days	MYOCARDITIS
DEPFIZER INC2021501482	1327866-1	Mar., 2021	2 days	MYOCARDITIS
DEPFIZER INC2021501490	1329807-1	Apr., 2021	2 days	MYOCARDITIS
DEPFIZER INC2021507764	1329837-1	Mar., 2021	3 days	MYOCARDITIS
DEPFIZER INC2021512315	1309874-1	Apr., 2021	5 days	MYOCARDITIS
DEPFIZER INC2021512461	1336443-1	Mar., 2021	2 days	MYOCARDITIS
DEPFIZER INC2021527843	1346312-1	Apr., 2021	6 days	MYOCARDITIS
DEPFIZER INC2021527920	1346328-1	Mar., 2021	2 days	MYOCARDITIS
DEPFIZER INC2021527946	1347928-1	Apr., 2021	5 days	MYOCARDITIS
DEPFIZER INC2021539544	1350326-1	Apr., 2021	3 days	MYOCARDITIS
DKPFIZER INC2021225745	1114602-1	Feb., 2021	1 day	MYOCARDITIS
ESPFIZER INC2021212898	1093082-1	Feb., 2021	2 days	MYOCARDITIS
FRPFIZER INC2021180588	1069408-1	Jan., 2021	0 days	MYOCARDITIS

Figure 7: Additional VAERS reports of myocarditis through May 2021, particularly within seven days.

A *new safety issue* for myocarditis was apparent at the time of the completed "5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports," received by the FDA from Pfizer on April 30, 2021. [https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf] Identification and communication of this concern at the time should have served as the initial adverse event warning announcement. Instead, the FDA waited until June 25, 2021, to issue a formal announcement – a two-month delay.

Report 40: "Is mRNA-LNP Vaccine-Induced Immunity Inheritable? A Preprint Study Shows It Is." – Monica Giannelli, PhD, and Lora Hammill.

Summary

Some traits acquired via the mRNA-LNP injections are passed genetically from parents to their offspring. The implications of this new finding are profound. Because of this inheritability, mRNA gene therapies – including mRNA "vaccines" – must be prohibited, at least until more is known, for expecting mothers as well as for parents who are planning to conceive children. As it becomes undeniable that mRNA treatments expose the general population to severe risks, no chances should be taken with unborn babies whose immune systems might be altered in irreversible ways.

Introduction

A preprint study by scientists with the Jefferson University in Philadelphia [Zhen Qi et al. (2022), https://www.biorxiv.org/content/10.1101/2022.03.16.484616v2] received significant attention, as it provides answers to a question many people have had since the roll out of the mRNA COVID vaccine: do the mRNA vaccines change the immune system?

After hundreds of millions of mRNA vaccines have been administered globally, fears of altered immune systems have proven justified and supported by recent studies. Zhen Qi et al. reference several articles, such as an important paper awaiting peer review, [Föhse et al. (2021), https://www.medrxiv.org/content/10.1101/2021.05.03.21256520v1], which show the Pfizer mRNA COVID vaccine reprograms both adaptive and immune responses. Another study [Arunachalam et al. (2021), https://pubmed.ncbi.nlm.nih.gov/34252919/] indicates significant changes in the immune system after receiving the Pfizer mRNA Covid vaccine.

Zhen Qi et al. shed light on some mechanisms of how mRNA vaccines change the immune system, by presenting experimental evidence that pre-exposure to mRNA-LNPs (Liquid Nanoparticles), or LNPs only, affects innate and adaptive immune system responses. The study indicates that LNPs, a critical component of mRNA vaccines, are responsible for modifying and weakening the immune system. Contrary to initial assessments, LNPs are not inert carriers or protectors of the mRNA. On the contrary, they are a highly inflammatory platform. Yet, they are critical in triggering adaptive immune responses [Ndeupen et al. (2021), https://pubmed.ncbi.nlm.nih.gov/34841223]. In fact, the altered immune responses appear to be caused by the inflammatory LNPs. This is consistent with earlier studies that linked inflammation to a poor responsiveness to vaccination, such as [Trzonkowski et al. (2003), https://pubmed.ncbi.nlm.nih.gov/12922116/].

The study also contains a revelation. The authors discovered that some acquired immune traits via the mRNA-LNP injections can be inherited by offspring. Even though the results are obtained for mice, it is conceivable humans might experience similar effects. The study raises urgent questions

about the safety of mRNA vaccines and should motivate further research to determine the true impact of the mRNA-LNP vaccines on the human immune system.

Experimental results

The first aim of Zhen Qi et al. study was to assess if a previous exposure to mRNA-LNPs influences the immune response to secondary vaccination. To prove this, they conducted several experiments on mice. The basic setup has three groups of mice: 1) the control group with mice injected with a placebo (i.e., a saline solution), 2) one group with mice injected with mRNA-LNPs coding for a harmless protein, and 3) one group injected with LNPs only.

The mice in the three groups were subsequently inoculated with mRNA-LNPs coding for influenza, and the mice immune responses were studied. The idea was that the mice were going to develop antibodies following the mRNA-LNP influenza shot (i.e., the mRNA-LNP coded for influenza is an mRNA flu vaccine).

The experimental results showed that adaptive immune responses of the mice injected either with mRNA-LNPs, or LNPs only, were inhibited compared to the mice injected with the placebo, showing reduced antibody, B-cell and T-cell responses. B and T-cells are part of the adaptive immune system and attack pathogens in a powerful and targeted way. There was no significant difference between the mice pre-exposed to mRNA-LNPs and those exposed to LNPs only, implying that LNPs play a significant role in the inhibition of the immune response. The authors found, "This inhibition of the adaptive immune responses was relatively long lasting, with effects seen for at least 4 weeks, while starting to wane after 8 weeks." Zhen Qi et al. observe this finding is in agreement with several studies that show mRNA vaccines have an improved antibody response if there is a longer time interval between subsequent injections.

There is some good news. The results in this study show that adjuvants – i.e., substances added to the vaccines for improvement – might remedy the immune-suppression induced by pre-exposure to mRNA-LNPs. However, to the best of these authors' knowledge, it is not clear if adjuvants have been considered or if they are at all viable for human mRNA vaccines.

The second aim of this research was to investigate the interaction between pre-exposure to mRNA-LNPs and subsequent infections. The authors found that mice pre-exposed to mRNA-LNPs have improved resistance if infected with influenza, but decreased resistance to Candida Albicans, a yeast infection. The resistance to influenza is surprising, since the mice injected with mRNA-LNPs showed a weak immune response after receiving the mRNA influenza shot. The stronger reaction to influenza is not due to an improvement of the immune system but likely is induced by the inflammatory LNPs. The increased vulnerability to Candida Albicans is an indication of impairment of the innate immune system. The authors experimentally confirmed that mice pre-exposed to mRNA-LNPs had a significantly lower percentage of neutrophils, the first line of innate defense for bacterial and fungal infections, which explained the vulnerability to Candida Albicans.

A third important result is that immune changes induced by pre-exposure to mRNA-LNP can be inherited. In mice injected with mRNA-LNP coding for influenza, the protection against influenza was successfully passed down to the offspring, with both male and female parents playing an important role. Zhen Qi et al. write "the highly inflammatory properties of the mRNA-LNP platform might have induced the inherited changes," as opposed to a strengthened immune system. Questions left unanswered in this study should prompt future research. The mechanism of inheritance is not understood, it is unknown how long after the exposure to mRNA-LNP that the parents can still pass down the immune traits, if the offspring's resistance to bacterial and fungal infections decreases, if the inherited immune changes alter the adaptive immune responses, and most importantly if humans are going to experience a similar genetic transmission.

Implications for humans

The results in this study give an indication of what humans are going to experience, since mice are routinely used in experiments to gain a preliminary understanding of how pathogens or drugs might affect humans. Inhibition of the immune responses following mRNA-LNP injections does not appear to be limited to mice. Zhen Qi et al. provide reference to several articles that show the resurgence of viral infections following a COVID-19 vaccination. A recent retrospective study found that vaccinated people might show a higher risk of infection than unvaccinated individual nine months post-vaccination [Nordstrom et al. (2022), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00089-7/fulltext]. A potential sign of immune suppression comes from reports of viral reactivation after the COVID-19 vaccination, such as Zoster Meningitis [Daouk et al. (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9239884/], Ramsay Hunt Syndrome [Woo et al. (2022), https://pmj.bmj.com/content/early/2022/01/05/postgradmedj-2021-141022], Epstein Barr virus [Herzum et al. (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9200649/] and Hepatitis C [Lensen et al. (2021), https://pubmed.ncbi.nlm.nih.gov/34512037/]. There is also increased risk for bacterial infections in open heart surgeries that could not be controlled with long-term antibiotic treatments, resulting in several deaths [Yamomoto, K (2022), https://pubmed.ncbi.nlm.nih.gov/35659687/].

Repeated mRNA-LNP shots inhibited mice immune system responses. It will be important to fully understand if this result can be applied to humans, especially with the deployment of Omicron boosters. (Some people will receive their fifth shot this fall.) Recent data from the vaccine surveillance report from the United Kingdom appear to be in agreement with the experimental results for mice. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1101870/vaccine-surveillance-report-week-35.pdf] In his September 7, 2022, Substack post, Alex Berenson writes, "The HSA (Health Security Agency) survey shows that almost everyone who is hospitalized with Covid in Britain has had at least two vaccine shots, including 87 percent of people 40-64, close to 95 percent of those 65 and over. The vast majority of those have had three shots.

Data this ugly explains why the White House is now proposing Americans get mRNA shots only once a year, a significant easing of previous pressure to get jabbed twice or even three times a year .” A significant takeaway of the report is that receiving multiple boosters has a negative effect on health, not unlike what was observed for the mice. Despite this worrisome data, Pfizer and Moderna do not show signs of slowing down; on the contrary they are racing to introduce new mRNA flu vaccines (Moderna and Pfizer start Phase 3 trial for flu mRNA vaccines, https://www.fiercebiotech.com/biotech/racing-moderna-pfizer-starts-phase-3-trial-mrna-flu-vaccine).

The most important finding of Zhen Qi et al. study is the genetic transmission of some traits acquired via the mRNA-LNP injections. The implications of this result for humans are profound if substantiated. Until then, it is these authors’ opinion that mRNA vaccines should be prohibited for expecting mothers and for parents who are planning to have a child. It is becoming clear mRNA vaccines expose the general population to unnecessary and severe risks, and no chances should be taken with unborn babies, whose immune systems might be in danger of being altered in a potentially irreversible way.

Report 41: "Failure of Serialization by Pfizer Flouted Established Pharma Rules" by Chris Flowers, MD.

Introduction:

There are strict protocols in place regarding the storage and distribution of all pharmaceuticals to ensure safety throughout the delivery process. Particularly for mRNA Covid vaccines that were distributed by billions worldwide, those protocols should have been carefully practiced. Dr. Chris Flowers has reported that not only were standard protocols waived in confidential contracts between Pfizer and a variety of countries, but also the sensitive nature of the mRNA encased in lipid nanoparticles requires a variety of technical factors that are extremely challenging to consistently follow.

Additionally, there are legal requirements in place to ensure tracking and quality assurance of every single dose of vaccine. Generally, each dose should receive its own unique serial number, in addition to being assigned to a specific batch and a specific lot of vaccines. In the case of the Pfizer mRNA vaccines, five doses were batched in each vial, leaving the onsite staff to dilute and measure out each dose.

Please read the following detailed report by Dr. Flowers for DailyClout for a comprehensive explanation of serialization.

Failure of serialization by Pfizer flouted established Pharma and Good Distribution Practice rules

Managing the quality of medical products as they are stored and distributed brings challenges with different storage requirements and expiry dates. As consumers, we cannot tell by sight or smell whether a drug has degraded during transport or been contaminated. Formalized Good Distribution Practices (GDP) are critical to the Pharma industry, being essential to ensuring that when medicines are ready to be administered, patients can be confident they are effective, unadulterated and safe to use.

Pfizer actively disregarded both legislation and guidance required by various countries for distribution of the COVID vaccine, insisting on exclusion clauses in the contracts. Why did they do this and where is the quality control for such a far-reaching intervention, like a vaccine for the world population?

What legislation is there regarding good manufacturing and distribution practice of pharmaceuticals?

The Drug Quality and Security Act (DQSA) was enacted by Congress on November 27, 2013 [FDA, 2015. *Drug Supply Chain Security Act.* [Online] Available at: https://www.fda.gov/media/93779/download [Accessed 17 September 2022]]. This required interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. Since November 2017, all pharmaceutical products were required to be serialized and compliant with the FDA's guidance. 'Track and Trace' in the pharmaceuticals industry is now seen as a *global* mandate. Compliance deadlines have been put into place [Movilitas Engineering Group, n.d. *DSCSA Compliance Deadlines and How to Prepare for Full Traceability.* [Online] Available at: https://www.movilitas.com/insights/dscsa-compliance-deadlines-and-how-to-prepare-for-full-traceability/. [Accessed 17 September 2022]].

What is Serialization and why is it important?

Serialization means that the manufacturer must apply a 2D barcode to *every unit* of finished product produced and then upload this manufacturing information to a central database. As the product moves through the distribution to the end user, the barcode is then scanned and can be checked for authenticity. In a process with multiple steps (units), each with a barcode, quality control can easily be maintained.

What are the benefits of Serialization?

Multiple benefits arise by following this process:

- Traceability – for each step of the manufacture
- An effective way to ensure brand authenticity and reduce batch recalls
- To assist with more efficient drug distribution
- Full compliance with government traceability regulations
- Potentially an end to counterfeit medicine

What exactly is supposed to be traced?

The FDA requires both a lot number and a batch number. Their definitions of these terms are as follows:

Batch means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

Lot number, control number, or batch number means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined [FDA, 2022. *CFR – Code of Federal Regulations Title 21.* [Online] Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=210.3 [Accessed 17 September 2022]].

What is Good Distribution Practice?

The U.S. Pharmacopeia (USP) is the source of many of the best practice guidelines (GxP) for distribution of products as regulated by the FDA. Similar documentation is provided by the UK Medicines and Healthcare products Regulatory Authority (MHRA) and the European Medicines Agency (EMA) [MHRA (Medicines and Healthcare products Regulatory Agency) 2017, 2017. *Rules and Guidance for Pharmaceutical Manufacturers and Distributors (The Orange Guide) eBook.* [Online]
Available at: https://www.pharmpress.com/product/9780857112910/orangeguide [Accessed 17 September 2022]].

- Good Distribution Practice (GDP) is one of the four pillars of essential good practices required to ensure medicinal products are produced to the approved license, to remain safe, effective and of the requisite quality.
- The other three pillars are Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP).
- Together, they make up the Pharmaceutical Quality Management System (QMS).
- GDP has become a critical element in the quality of medicinal products produced, as supply chains have globalized and biologics, living things that are sensitive to environmental changes, have grown with the advent of monoclonal antibodies and gene therapies.
- Regulatory Authorities (FDA/EMA/MHRA) are required to inspect for compliance with GDP across all companies registered as a component of the clinical and/or commercial supply chain.

There are many elements that make up good distribution practice, and here are just a few of them –

- The Pharmaceutical Quality System
- Premises and Equipment
- Documentation
- Operations
- Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls
- Self-Inspections
- Transportation

How does this relate to the COVID vaccine manufacture?

Most vaccines in the USA are provided as single dose vials or pre-filled syringes, but the mRNA/Lipid Nanoparticle platform developed for this vaccine was packaged into multiple dose vials for shipping around the World [Joshua Eaton, N. N., 2021. *The U.S. is discarding millions of Covid vaccines. One cause: Multi-dose vials.* [Online] Available at: https://www.nbcnews.com/news/us-news/u-s-discarding-millions-covid-vaccines-one-cause-multi-dose-n1279901. [Accessed 17 September 2022]]. This applies to both Pfizer and Moderna products.

Manufacture of the COVID vaccine is complex, a trade secret and has many components (inputs), which would have lot and batch numbers for each part. Quality control is a major issue given that mRNA is very unstable, reported by the European Medicines Agency and published in the British Medical Journal (BMJ) [Serena Tinari, B., 2021. *The EMA covid-19 data leak, and what it tells us about mRNA instability.* [Online] Available at: https://www.bmj.com/content/372/bmj.n627 [Accessed 17 September 2022]] and the LNP platform is tricky to get right consistently, both for the size of the particles and the distribution of mRNA within them [Christo T. Tzachev, H. L. S., 2012. *Lipid Nanoparticles at the Current Stage and Prospects – A Review Article.* [Online] Available at: https://www.globalresearchonline.net/journalcontents/v18-1/15.pdf [Accessed 17 September 2022]].

Furthermore, there are technical issues with the mRNA/LNP platform which require Ultra low-temperature freezers to maintain the integrity of these lipid particles, as they are subject to oxidative degradation where the lipids form into clumps. Indeed, there are many issues with the LNP storage and transport, as they can be easily destroyed by vigorous shaking, including using road transport.

At the start of vaccine production, the where and how that the mRNA was manufactured is a source of controversy, and documentation of the early days is not readily available. At a certain date, Pfizer started a group of factories within the USA making the different stages of the vaccine: Chesterfield, MO where the Antigen DNA was manufactured, then Andover, MA where mRNA was made followed by Portage, MI where the LNPs are combined with the mRNA which takes around four days [Elizabeth Weise, K. W., 2021. *A COVID-19 vaccine life cycle: from DNA to doses.* [Online] Available at: https://eu.usatoday.com/in-depth/news/health/2021/02/07/how-covid-vaccine-made-step-step-journey-pfizer-dose/4371693001/. [Accessed 17 September 2022]]. After that, they were combined into the LNPs and packaged into 5 dose vials. This is the 'finalized' product leaving the manufacturer which the rules require to be serialized with a barcode.

Serialization requires barcoding for every FINALIZED dose of medicine, and each individual dose should have been given a lot and batch number, but this could not possibly happen with either the Pfizer or Moderna vaccines, because they left the manufacturer frozen and in vials containing five or six doses, rather than single doses. Furthermore, each separate dose of the vaccines was not done by

the manufacturer but finalized on-site by diluting the five-dose vial with saline and drawing up into individual syringes for injection.

Questions have been raised regarding the monitoring of quality control of COVID vaccine manufacture, which is not just a Pfizer issue, as other manufacturers had bad batches that had to be withdrawn, due to contamination. Here are two examples:

1. 60 million doses of Johnson and Johnson vaccine made at their Baltimore plant had to be withdrawn [Burroughs, D., 2021. *FDA Finds 60 Million COVID Vaccine Doses Were Potentially Contaminated: Report.* [Online].
   Available at: https://www.westernjournal.com/fda-finds-60-million-covid-vaccine-doses-potentially-contaminated-report/[Accessed 17 September 2022]].
2. Another example occurred in Japan, where a batch of Moderna mRNA vaccine had to be recalled due to apparent contamination [Guenot, M., 2021. *Japan investigating whether 3 deaths are linked to a Moderna vaccine batch that officials fear was contaminated.* [Online]
   Available at: https://www.businessinsider.com/three-dead-recalled-contaminated-batch-investigation-japan-moderna-2021-9?op=1&r=US&IR=T. [Accessed 17 September 2022]].

How did we learn that there was a contractual issue with Serialization and Pfizer?

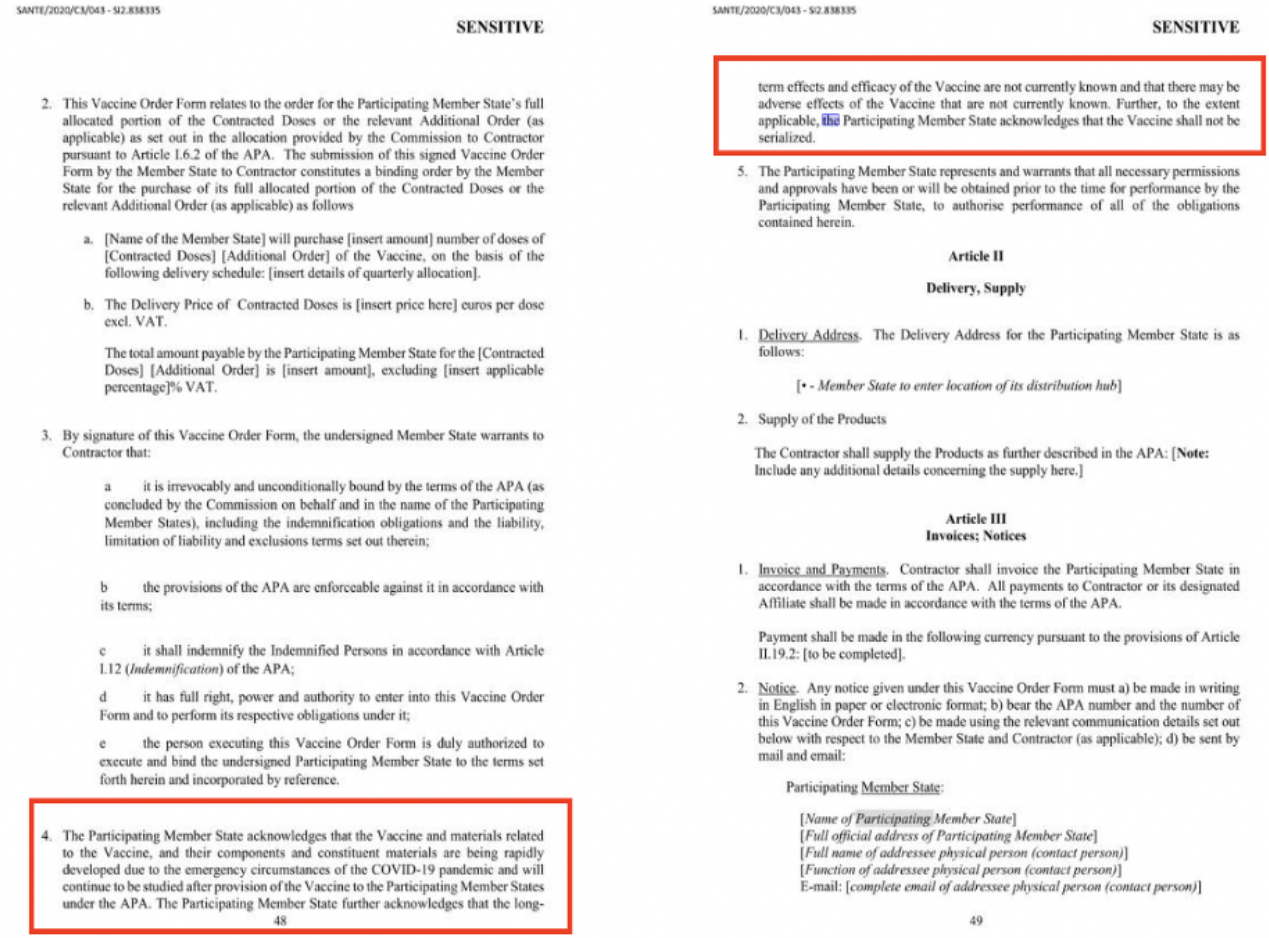
This revelation happened due to the leaking of an unredacted contract between Pfizer and the European Union. Originally reported by Reuters and multiple news media in April 2021, Pfizer had 73 formalized deals with countries around the world for its COVID-19 vaccine at that time. But of those, only five had been published by governments and they included *'significant redactions*.' Apart from charging different prices in different countries, they also included a phrase '*the Participating Member State acknowledges that the Vaccine shall not be serialized*.' The Contract between Pfizer and the European Union was termed an Advance Purchase Agreement [Pfizer, E. C. a., 2021. *Contract Between the European Commission and Pfizer (Manufacturing And Supply Agreement).* [Online]
Available at: https://archive.org/details/contract_03 [Accessed 17 September 2022]].

The contract between the European Commission and Pfizer was leaked in March 2021 to a Belgian association, Notre Bon Droit.

ADVANCE PURCHASE AGREEMENT ("APA")[1] for the development, production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member States

SANTE/2020/C3/043 - SI2.838335

Title page of *Contract Between the European Commission and Pfizer*.



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2. This Vaccine Order Form relates to the order for the Participating Member State's full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) as set out in the allocation provided by the Commission to Contractor pursuant to Article I.6.2 of the APA. The submission of this signed Vaccine Order Form by the Member State to Contractor constitutes a binding order by the Member State for the purchase of its full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) as follows

   a. [Name of the Member State] will purchase [insert amount] number of doses of [Contracted Doses] [Additional Order] of the Vaccine, on the basis of the following delivery schedule: [insert details of quarterly allocation].

   b. The Delivery Price of Contracted Doses is [insert price here] euros per dose excl. VAT.

   The total amount payable by the Participating Member State for the [Contracted Doses] [Additional Order] is [insert amount], excluding [insert applicable percentage]% VAT.

3. By signature of this Vaccine Order Form, the undersigned Member State warrants to Contractor that:

   a it is irrevocably and unconditionally bound by the terms of the APA (as concluded by the Commission on behalf and in the name of the Participating Member States), including the indemnification obligations and the liability, limitation of liability and exclusions terms set out therein;

   b the provisions of the APA are enforceable against it in accordance with its terms;

   c it shall indemnify the Indemnified Persons in accordance with Article I.12 (*Indemnification*) of the APA;

   d it has full right, power and authority to enter into this Vaccine Order Form and to perform its respective obligations under it;

   e the person executing this Vaccine Order Form is duly authorized to execute and bind the undersigned Participating Member State to the terms set forth herein and incorporated by reference.

4. The Participating Member State acknowledges that the Vaccine and materials related to the Vaccine, and their components and constituent materials are being rapidly developed due to the emergency circumstances of the COVID-19 pandemic and will continue to be studied after provision of the Vaccine to the Participating Member States under the APA. The Participating Member State further acknowledges that the long-

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term effects and efficacy of the Vaccine are not currently known and that there may be adverse effects of the Vaccine that are not currently known. Further, to the extent applicable, the Participating Member State acknowledges that the Vaccine shall not be serialized.

5. The Participating Member State represents and warrants that all necessary permissions and approvals have been or will be obtained prior to the time for performance by the Participating Member State, to authorise performance of all of the obligations contained herein.

Article II

Delivery, Supply

1. Delivery Address. The Delivery Address for the Participating Member State is as follows:

   [• - *Member State to enter location of its distribution hub*]

2. Supply of the Products

   The Contractor shall supply the Products as further described in the APA: [**Note:** Include any additional details concerning the supply here.]

Article III
Invoices; Notices

1. Invoice and Payments. Contractor shall invoice the Participating Member State in accordance with the terms of the APA. All payments to Contractor or its designated Affiliate shall be made in accordance with the terms of the APA.

   Payment shall be made in the following currency pursuant to the provisions of Article II.19.2: [to be completed].

2. Notice. Any notice given under this Vaccine Order Form must a) be made in writing in English in paper or electronic format; b) bear the APA number and the number of this Vaccine Order Form; c) be made using the relevant communication details set out below with respect to the Member State and Contractor (as applicable); d) be sent by mail and email:

   Participating Member State:

   [*Name of Participating Member State*]
   [*Full official address of Participating Member State*]
   [*Full name of addressee physical person (contact person)*]
   [*Function of addressee physical person (contact person)*]
   E-mail: [*complete email of addressee physical person (contact person)*]

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Contract Between the European Commission and Pfizer – pp. 48 and 49.

This piqued the interest of members of the European Parliament who noted unusual legal requests by Pfizer in the contract and they made formal requests for information [(ID), G. R., 2021. *Parliamentary question – E-002296/2021.* [Online] Available at: https://www.europarl.europa.eu/doceo/document/E-9-2021-002296_EN.html [Accessed 17 September 2022]]. The narrative shared by news media focused on different pricing between jurisdictions and lack of accountability/limitations of liability. The unusual legal requests about formal serialization were overlooked.

How do the GDP (distribution) rules intersect with the absence of serialization of the vaccine?

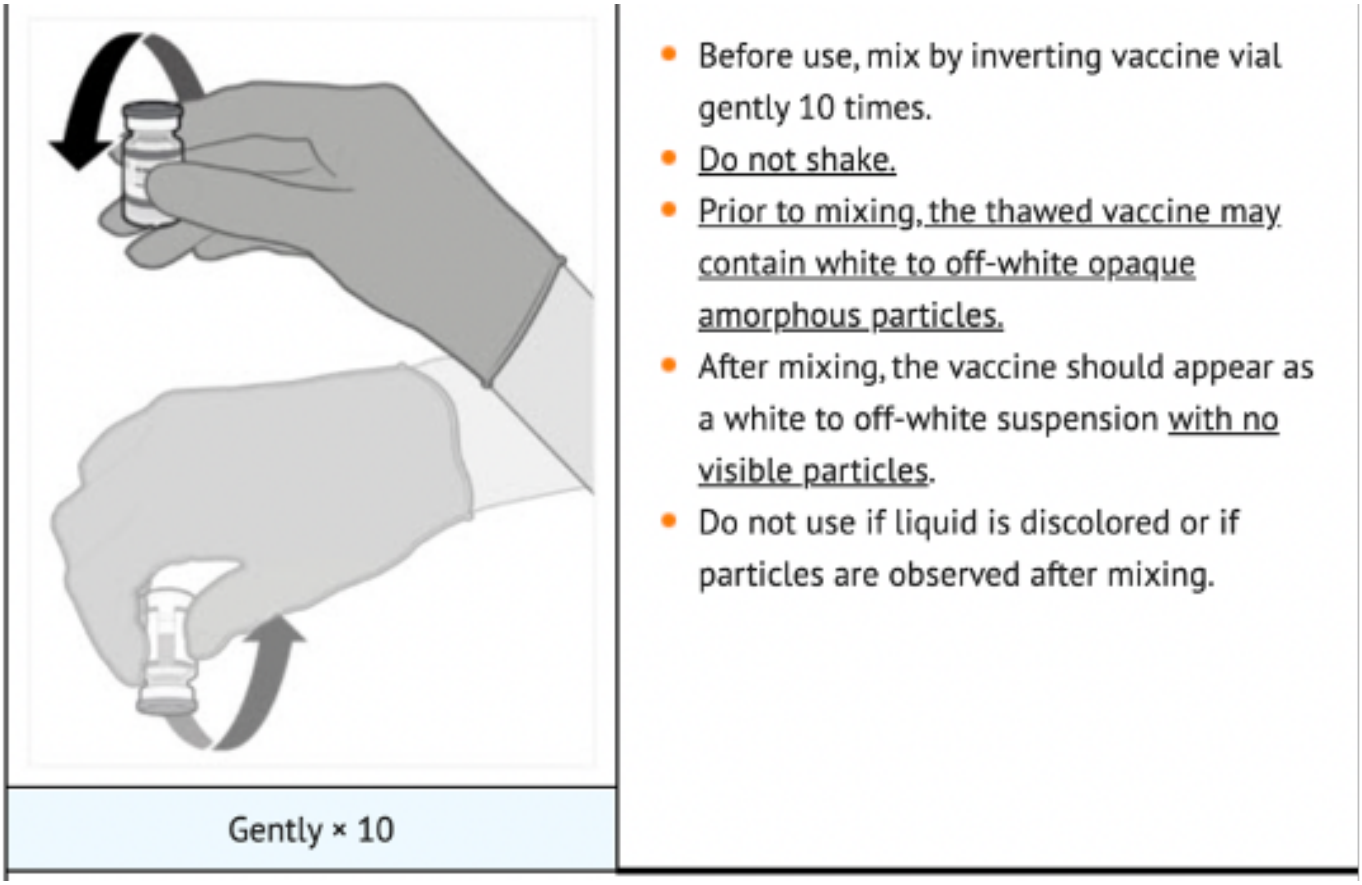
All components of the COVID vaccine should have been given both lot and batch numbers during manufacture and once the mRNA was incorporated into the lipid nanoparticles and placed into vials, they should have been assigned a serialized barcode, according to standard practice.

When it comes to distribution, barcodes are required to manage the safe flow of the product to its destination. Licensed wholesale distributors must comply with GDP, but uniquely for this type of vaccine, they had to be stored and shipped at Ultra-low temperatures (deep frozen down to minus 112 degrees F) and protected from vibration. Due to the uniqueness of this platform, the distribution networks were inadequate, and an alternative was used, bypassing the normal regulated networks of distribution. As a result, by using a novel distribution method rather than the normal wholesale distribution network, the vaccine escaped the safety mechanisms that other pharmaceuticals are mandated to follow.

Other potential issues arise with a multi-dose LNP vaccine when it is time to be administered?

First described in the clinical trials protocol, and later in the instructions for use in the commercial product, there were strict instructions for use, which most medical staff would be unfamiliar with, compared with a regular injection.

The vials had to be stored locally in a freezer and then the vials had to be thawed within a strict usage window of 2 weeks. Before use, the vials had to be thawed, mixed with saline and inverted *gently* 10 times before use, not shaken and then discarded after 6 hours [DailyMed, 2022. *LABEL: COMIRNATY- covid-19 vaccine, mrna injection, suspension.* [Online] Available at: https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=48c86164-de07-4041-b9dc-f2b5744714e5#section-2.1 [Accessed 17 September 2022]].



The gentle inversion allowed mixing of the saline and LNPs to make a smooth white suspension. If the right amount of inversion had not been performed, then each dose could have a different concentration of mRNA. If the vials were shaken, there is a chance that the LNPs would have been disrupted and some LNPs may not contain mRNA and others may contain a higher dose.

What does all this mean for us?

Unlike normal regulated pharmaceutical products, the multi-dose vaccine does not have the basic manufacturing information and required codes needed to provide the expected quality control of a Pharma product, including consistency in dosing, due to requirements of not having a finalized product.

If we are to trust vaccine manufacturers in the future, good quality control needs to be established as with other medical products, with full transparency of the ingredients and potential adverse effects, including severe ones that will allow us to give informed consent.

The use of multi-dose vaccine vials which need reconstituting with saline should cease, and barcoded, single-use, pre-filled syringes should be standard practice.

Report 42: "How Many Pregnant American Women Received mRNA COVID-19 Vaccines in 2021? Only Estimates Are Available." – Robert W. Chandler, MD, MBA.

Estimates of the Number of Pregnant Women Receiving LNP/mRNA by COVID-19 Vaccine During Year 2021

I. Searching for the Denominator

Prospective studies of pregnant women who received lipid nanoparticle plus messenger ribonucleic acid (LNP/mRNA) injections for prevention of COVID-19 during 2021 were scant, leading to difficulty in computing rates of spontaneous abortion, stillbirth, congenital anomaly, perinatal fatality, prematurity and small gestational size.

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) published the results of their surveillance of pregnant women in 2021. (https://www.nejm.org/doi/full/10.1056/NEJMoa2104983?query=recirc_curatedRelated_article)

Using the v-safe registry, Shimabukuro, et al. reported on 35,691 pregnant women who received at least one dose of LNP/mRNA during pregnancy. Of these, 3,958 were included in the Pregnancy Registry, and 127 were identified as having been inoculated during their first two trimesters and then completed their pregnancies.

These numbers were published in the *New England Journal of Medicine* (*NEJM*) in April, June, and October of 2021 with no additional entries or expansion of the data set other than a separate subject group reported by Zauche, et al. in August of 2021. The Zauche, et al. data set only had data through 20 weeks gestation, did not include the first six weeks of gestation, and was a small, non-representative sample that was not updated as the pregnancies proceeded to term. (https://dailyclout.io/data-do-not-support-safety-of-mrna-covid-vaccination-for-pregnant-women/, https://dailyclout.io/report-40-2021-cdc-and-fda-misinformation-retroactive-editing-erroneous-spontaneous-abortion-rate-calculation-obfuscation-in-the-new-england-journal-of-medicine/, https://pubmed.ncbi.nlm.nih.gov/2021664/%5d, https://pubmed.ncbi.nlm.nih.gov/3393170/, https://www.ncbi.nlm.nih.gov/books/NBK560521/)

Unfortunately, the rates of spontaneous abortion, stillbirth, congenital anomaly, perinatal fatality, and small gestational size could not be calculated since a suitable denominator was not available. (https://dailyclout.io/report-40-2021-cdc-and-fda-misinformation-retroactive-editing-erroneous-spontaneous-abortion-rate-calculation-obfuscation-in-the-new-england-journal-of-medicine/)

The takeaway from the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) reporting is that there was no useful surveillance of pregnant women who

received the genetic therapy represented by BNT162b2, Pfizer's mRNA COVID vaccine, and/or mRNA1273, Moderna's mRNA COVID vaccine, that would allow determination of safety of these products during pregnancy.

The question arises as to how many American pregnant women were injected during 2021, the first full year of Emergency Use Authorization (EUA) of mRNA COVID vaccines.

What follows is an attempt to answer that question by computation, as the actual data has not been made available if it even exists.

II. Definitions:

- FL_{20} = Fetal loss at 20 weeks or later, also called Stillbirth.
- LB = Live Births.
- P = Pregnancies.
- SAB = Spontaneous Abortions, also called Miscarriage, defined as spontaneous fetal loss before 20 weeks.
- SABr = Rate of Spontaneous Abortion or SAB/P
- TAB = Therapeutic Abortions; abortions that involve assistance from the medical profession and are done electively, urgently and emergently.
- TFL = Total Fetal Loss; the sum of (FL_{20} + SAB + TAB).

III. Calculation of the Number of Pregnancies in 2021 (See Appendix I)

Pregnancies (P) are the sum of the number of live births (LB), therapeutic abortions (TAB), spontaneous abortions (SAB), and fetal loss at 20 weeks or later (FL_{20}):

$$P = LB + TAB + FL_{20} + SAB$$

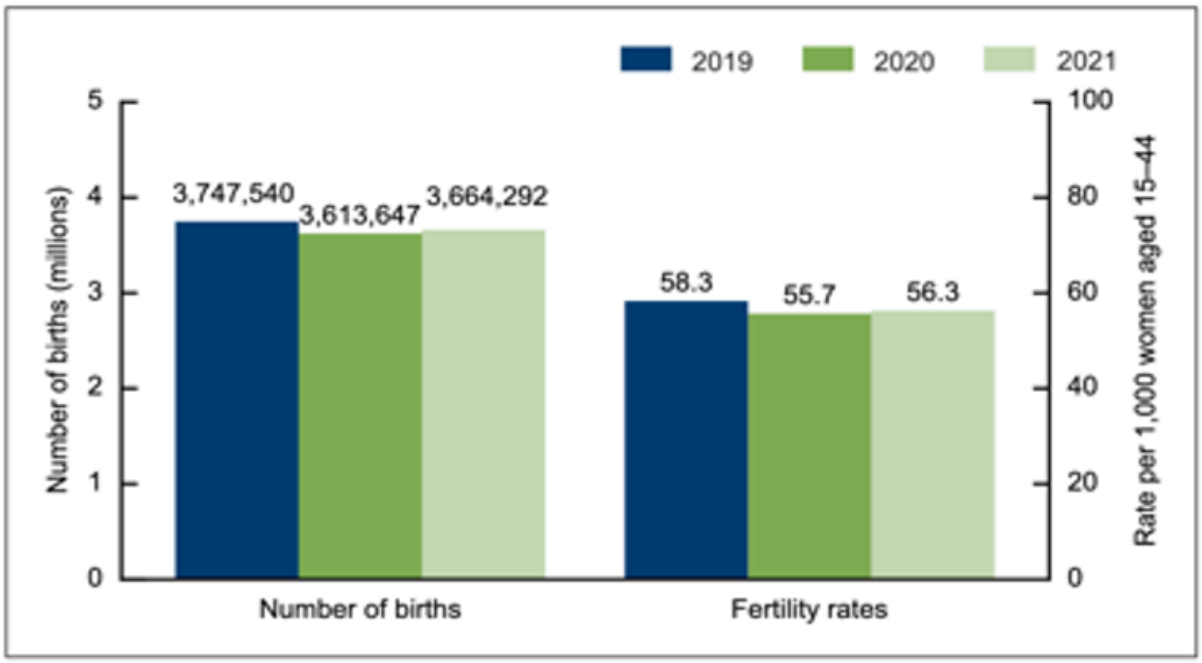
$$\text{Total Fetal Loss (TFL)} = TAB + FL_{20} + SAB$$

$$\therefore P = LB + TFL$$

A. 2021 Live Births:

According to the CDC (https://www.cdc.gov/nchs/data/databriefs/db442.pdf), there were ***3,664,292*** live births in 2021, up 1% from 2020 and down 2% from 2019. Figure 1.

Figure 1. Number of live births and general fertility rates: United States, 2019–2021



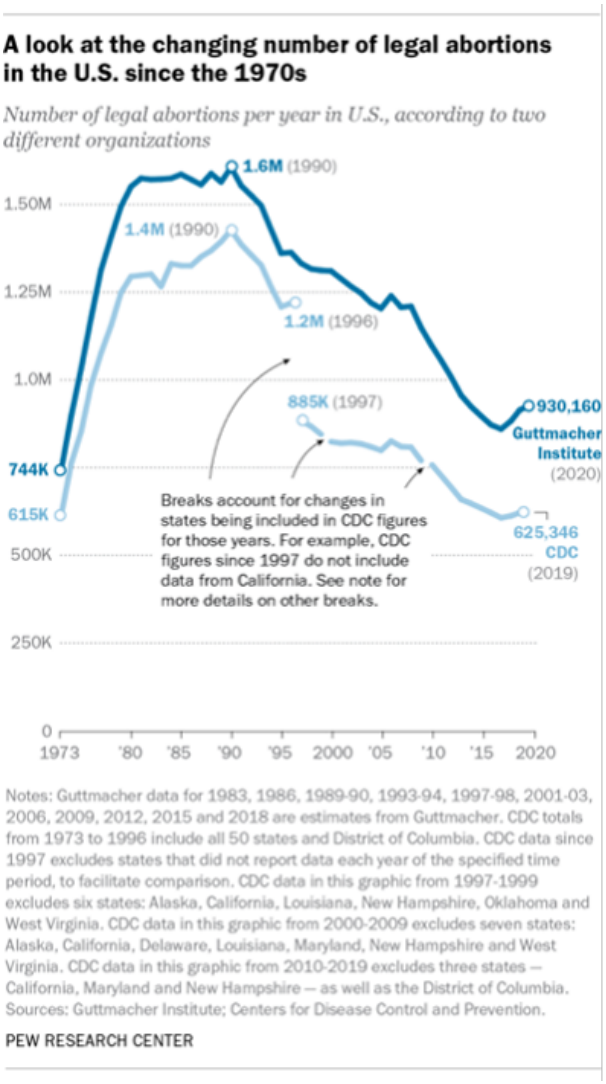
NOTES: Significant decrease in the number of births and the general fertility rate from 2019 to 2020 ($p < 0.05$). Significant increase in the number of births and the general fertility rate from 2020 to 2021 ($p < 0.05$). Rates for 2020 have been revised and may differ from those published in "Births: Final Data for 2020." Rates are based on counts enumerated as of April 1 for census year 2020 and estimated as of July 1 for 2019 and 2021. Access data table for Figure 1 at: https://www.cdc.gov/nchs/data/databriefs/db442-tables.pdf#1.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Natality.

B. 2020 Therapeutic Abortions (TAB):

The CDC estimates the number of therapeutic abortions in 2019 as 625,346, while the Guttmacher Institute estimated the number the last year data were available in 2020 to be ***930,160***. (https://www.pewresearch.org/fact-tank/2022/06/24/what-the-data-says-about-abortion-in-the-u-s-2/ft_2022-06-23_abortiondata_01/)

Figure 2 displays the discrepancy between the estimates of therapeutic abortions from the CDC and the Guttmacher Institute.

Figure 2: US TABs



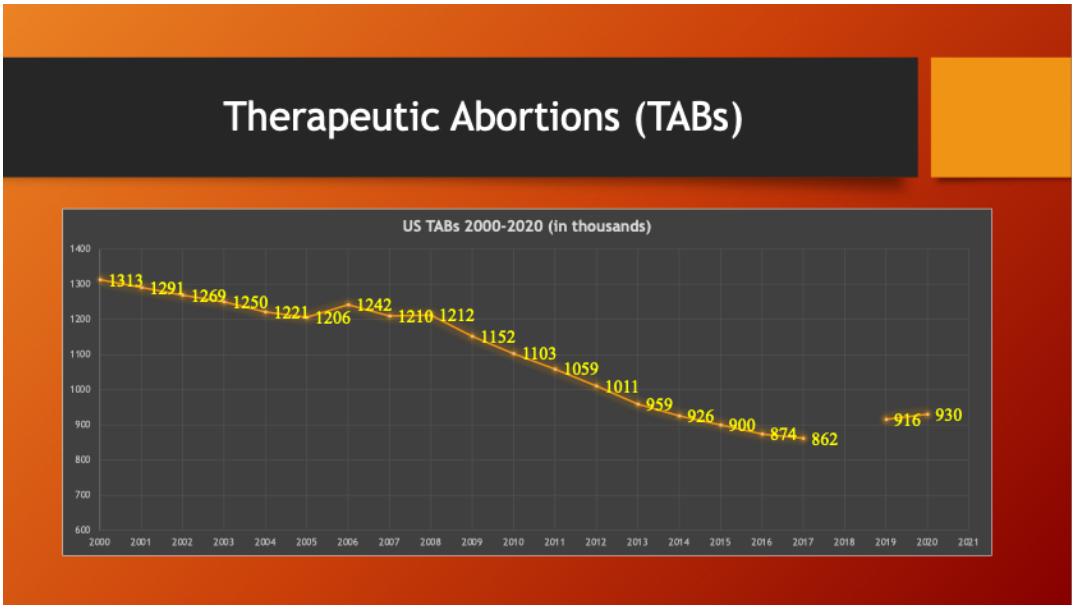
This discrepancy is explained as follows:

> "The Guttmacher Institute compiles its figures after contacting every known provider of abortions – clinics, hospitals and physicians' offices – in the country. It uses questionnaires and health department data, and it provides estimates for abortion providers that don't respond to its inquiries. In part because Guttmacher includes figures (and in some instances, estimates) from all 50 states, its totals are higher than the CDC's." (https://www.guttmacher.org/united-states/abortion)

Guttmacher TAB estimates are used in this article as they are more complete than those from the CDC.

Chart 1 illustrates a 42% decline in therapeutic abortions from their peak at 1.6 million in 1990 compared with 930,000 in 2020 and 46% from the peak in 1990 to a modern low in 2017 of 862,000.

Chart 1: Decline in TABs Since 2000.



C. Fetal Loss at 20 Weeks or Later (FL_{20}) (Stillbirths):

2020 Data from the CDC gives the FL_{20} as ***20,854***.
(https://www.cdc.gov/nchs/data/nvsr/nvsr71/nvsr71-04.pdf)

D. Pregnancy and Spontaneous Abortion Calculation:

Spontaneous abortions are estimated to occur in 10 to 30 percent of pregnancies:

> "Vaginal bleeding before twenty weeks of gestation occurs in up to 20% of pregnancies, and 50% of these cases will have a spontaneous abortion. Overall, 10-20% of clinically recognized pregnancies will end in early pregnancy loss. However, these statistics likely underestimate the true incidence of spontaneous abortion, as many miscarriages occur before a mother realizes she is pregnant and is simply mistaken as heavy, late menses. As a result, ***the true incidence of spontaneous abortion may be closer to 30%.***"
> (https://www.ncbi.nlm.nih.gov/books/NBK560521/)

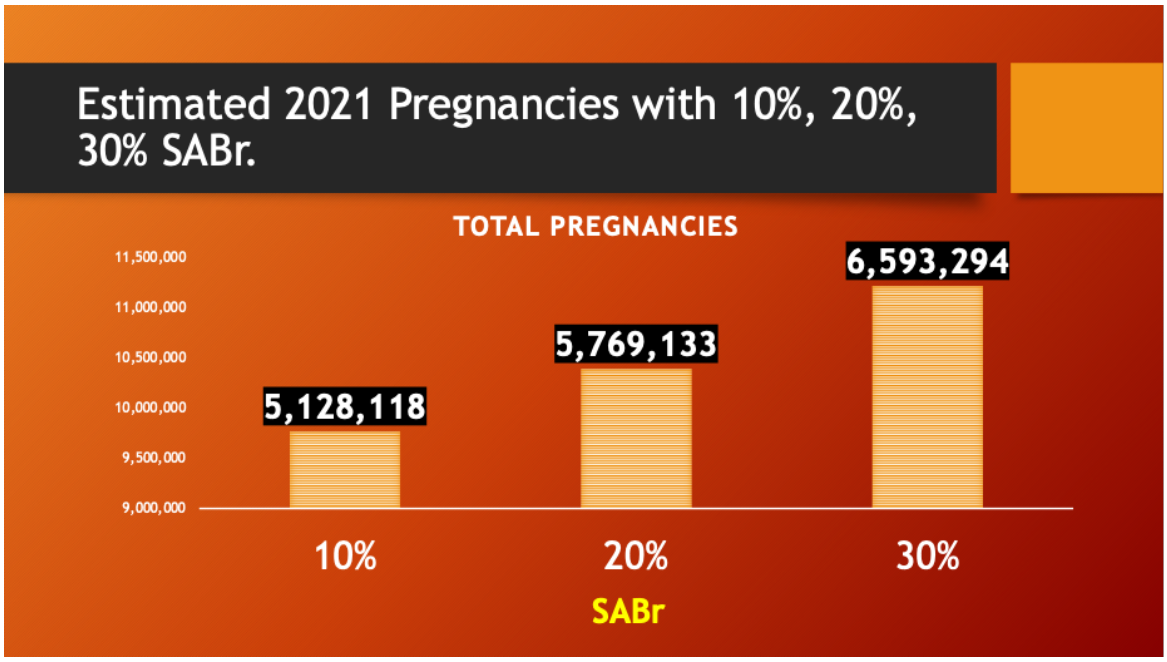
Given the variance in reported SABr, calculations were made using 10%, 20% and 30% in estimating the number of pregnancies in 2021.

A tool (Appendix I) to calculate a value for pregnancies was developed using the following equation,

$$P = (LB + TAB + FL_{20})/(1-r)$$

Where r = SABr, the rate of spontaneous abortion. r values considered here are 0.1, 0.2 and 0.3 for 10%, 20% and 30%.

Chart 2: Estimated Number of Pregnancies in 2021.



The range in the estimated number of pregnancies in 2021 is from ***5,128,118 to 6,593,294.*** Given that the lower figure of 10% does not commonly take into account the first six weeks of gestation, the 20 to 30% range for SABr is more likely to encompass the ***true range of pregnancy of 5.8 to 6.6 million pregnant women in 2021*** than the 10 to 20% figure that is commonly quoted. (Goldhaber, M. K., & Fireman, B. H. (1991). The fetal life table revisited: spontaneous abortion rates in three Kaiser Permanente cohorts. *Epidemiology (Cambridge, Mass.)*, *2*(1), 33–39. https://pubmed.ncbi.nlm.nih.gov/2021664. Wilcox, A. J., Weinberg, C. R., O'Connor, J. F., Baird, D. D., Schlatterer, J. P., Canfield, R. E., Armstrong, E. G., & Nisula, B. C. (1988). Incidence of early loss of pregnancy. *The New England Journal of Medicine*, *319*(4), 189–194. https://pubmed.ncbi.nlm.nih.gov/3393170/)

This is a reasonable estimate when compared with the Guttmacher.org 2017 estimate of ***5,573,550***. (https://data.guttmacher.org/states/)

IV. Estimates of Pregnant Women (PW) Who Were Given LNP/mRNA in 2021

As of December 30, 2021, USA Facts provided the following numbers for the percent of the US population receiving COVID-19 gene therapy products.

US Total Vaccines 2021:

1 dose	73%	243,527,564
2 doses	62%	205,811,394
3 doses	20%	68,810,709

(https://usafacts.org/visualizations/covid-vaccine-tracker-states/)

The 20% and 30% estimates of SABr will be used to calculate the number of pregnant women injected with LNP/mRNA products in 2021. Appendix II gives the details of these estimates.

Chart 3 illustrates ranges of values for rates of LNP/mRNA injection for the 20% and 30% SABr cases using 25%, 50%, and 100% of the general public rates (GPr) of inoculation.

Chart 3: All Trimesters

All Trimesters: Estimated Number of Pregnant Women (PW) Injected with LNP/mRNA in 2021

All Trimesters		
1 Dose	20% SABs	30% SABs
100% GPr	4,211,467	4,813,105
50% GPr	2,105,733	2,406,552
25% GPr	1,052,867	1,203,276
Range	1,052,867	4,813,105
2 Doses	20% SABs	30% SABs
100% GPr	3,576,862	4,087,842
50% GPr	1,788,433	2,043,921
25% GPr	894,215	1,021,961
Range	894,216	4,087,842

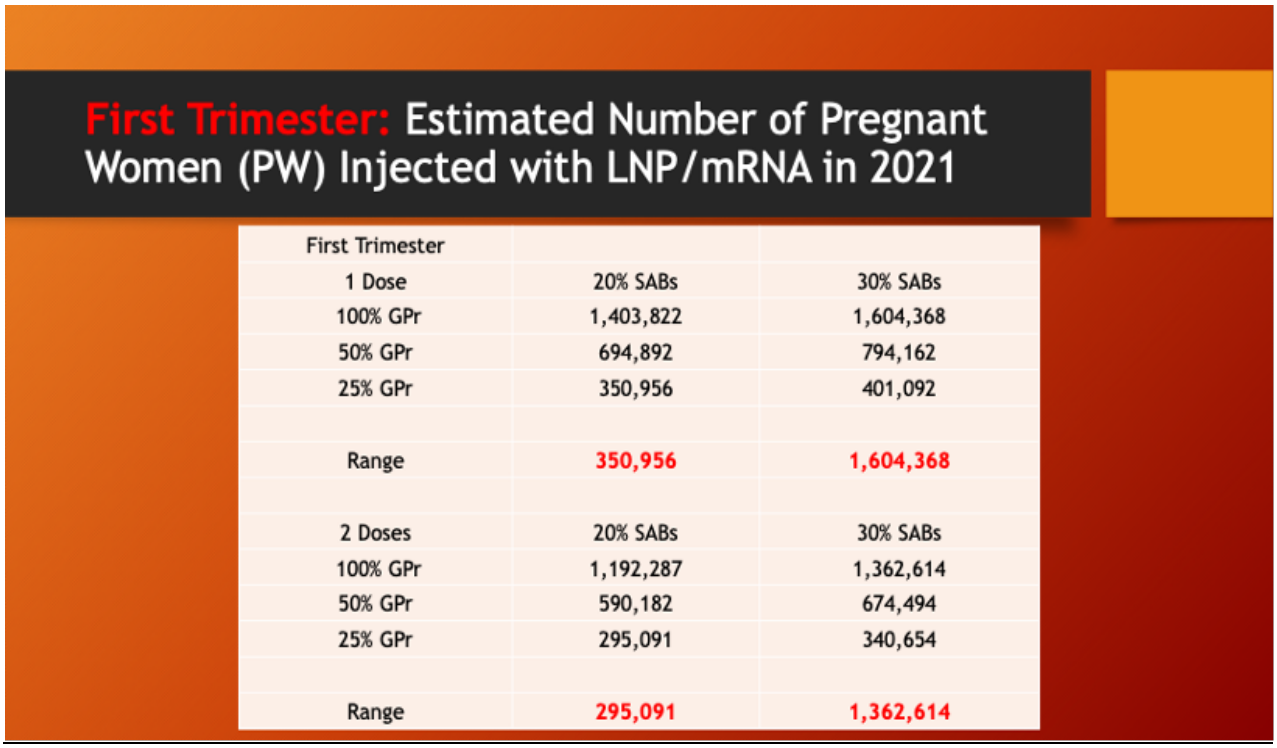
From this analysis, the estimated total number of pregnant women injected with one or two doses of LNP/mRNA during 2021 ranges from:

894,216 two doses at 25% general population vaccination rate

4,813,105 one dose at 100% of general population vaccination rate

The first trimester is the critical time when a fetus is at maximum risk for harms from various agents such as alcohol, pharmaceuticals, and radiation to give a few examples. (https://www.hopkinsmedicine.org/health/wellness-and-prevention/the-first-trimester) The first trimester case is considered in Charts 4 and 5.

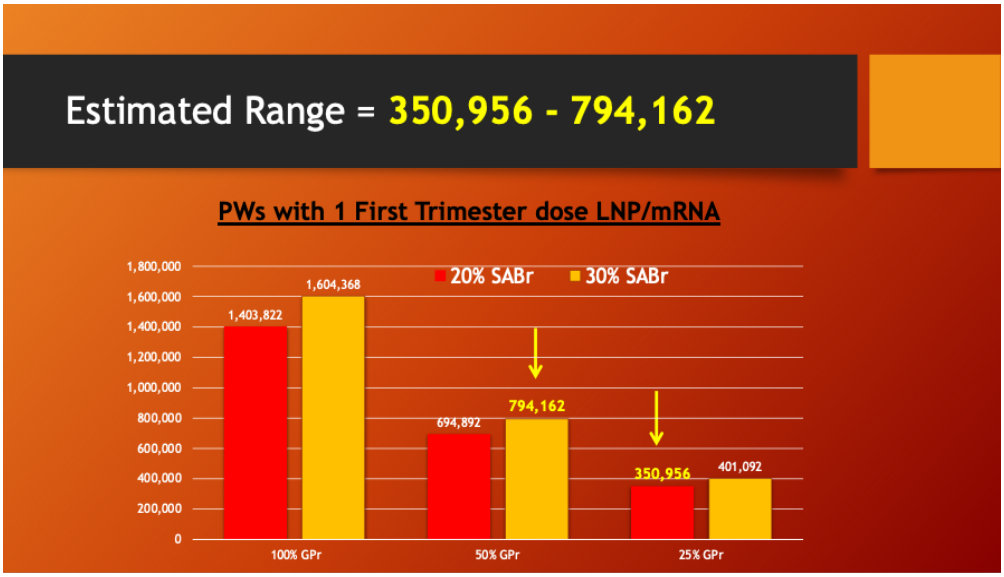
Chart 4: First Trimester Estimates



First Trimester		
1 Dose	20% SABs	30% SABs
100% GPr	1,403,822	1,604,368
50% GPr	694,892	794,162
25% GPr	350,956	401,092
Range	350,956	1,604,368
2 Doses	20% SABs	30% SABs
100% GPr	1,192,287	1,362,614
50% GPr	590,182	674,494
25% GPr	295,091	340,654
Range	295,091	1,362,614

Even though no cautions were issued by government health care agencies or the medical establishment concerning first trimester injections of experimental LNP/mRNA gene products, obstetricians have historically been very cautious about recommending any medication during the first trimester of pregnancy. Therefore, the true number of pregnant women injected with at least one dose of LNP/mRNA during their first trimester is likely to have been in the mid- to lower-end of this range, ***350,956 to 794,162***.

Chart 5: Best Estimate of the Number of Pregnant Women Who Received One Dose of LNP/mRNA During Their First Trimester



V. Discussion:

The crudeness of these estimates must be acknowledged. Some assumptions are built into this analysis that may be incorrect. Figures from 2021 will be used to update these calculations when they become available.

There is wide variation in the estimated number of pregnant women given LNP/mRNA during their pregnancies, but the potential is that as many as ***4.8 million pregnant American women*** were injected in 2021 with at least 1 dose (see Chart 3) of LNP/mRNA during any trimester and up to **800,000 in the critical first trimester.**

Unfortunately, US government health agencies have made no serious attempt to study the pregnant women who were injected with LNP/mRNA in 2021, and efforts must now be made to study the outcome of these pregnancies. (https://dailyclout.io/data-do-not-support-safety-of-mrna-covid-vaccination-for-pregnant-women/, https://dailyclout.io/report-40-2021-cdc-and-fda-misinformation-retroactive-editing-erroneous-spontaneous-abortion-rate-calculation-obfuscation-in-the-new-england-journal-of-medicine/)

Medical professionals must be surveyed to learn of the advice they gave to their pregnant patients, and the patients who received LNP/mRNA during their pregnancies must be located to determine outcomes.

At this point in time, the long-term effects of LNP/mRNA are unknown in the general population as well as in pregnant women. The latter group, however, represents a very special class, as not only are two human beings at risk but, even more profoundly if that is possible, future generations may have inherited experimental mRNA from their parents.

Already there is some evidence that synthetic mRNA can be translated into host DNA, which in turn can incorporate into the genome where it may produce a myriad of heritable and unwelcome biologic changes. (https://www.mdpi.com/1467-3045/44/3/73/htm)

In addition to the potential for generational transmission of synthetic, manmade genetic code, there are concerns over ongoing production of novel proteins that can lead to autoimmunity, the vascular disorders of clotting and embolus, dysregulation of oncogenes and cancers, myeloproliferative disorders, and the various expressions of prion disease including degenerative neurologic disease. (https://www.theepochtimes.com/health/why-spike-protein-causes-abnormal-blood-clots-200-symptoms_4842684.html, https://www.theepochtimes.com/health/more-adverse-events-its-time-to-halt-covid-vaccine-recommendations-for-pregnant-women_4824656.html, and https://www.theepochtimes.com/spike-protein-in-covid-19-vaccines-triggering-cancers-and-clots-pathologist-dr-ryan-cole_4820381.html)

At this point, the damage has been done. The experiment, like a bold journey into an unknown and potentially hostile realm, has launched. The means to study the effects of these novel gene therapy products exist but have been severely suppressed by an unseen and powerful international agent that seemingly acts in its own interest and not that of humanity. Not since the era of the Third Reich has the world witnessed diabolic intent on this level.

"To a large degree, the medical profession was not politicized but politics were medicalized."
(E. Ernst, Commentary: The Third Reich—German physicians between resistance and participation, *International Journal of Epidemiology*, Volume 30, Issue 1, February 2001, Pages 37–42, https://doi.org/10.1093/ije/30.1.37)

Appendix I: Calculation of Spontaneous Abortion (Miscarriage)

Definitions:

- FL_{20} = Fetal loss at 20 weeks or later, also called Stillbirth.
- LB = Live Births.
- P = Pregnancies.
- SAB = Spontaneous Abortions, also called Miscarriages, defined as spontaneous fetal loss before 20 weeks.
- SABr = Rate of Spontaneous Abortion or SAB/P.

- TAB = Therapeutic Abortions; abortions that involve assistance from the medical profession and are done electively, urgently and emergently.
- Total Fetal Loss; the sum of (FL_{20} + SAB + TAB).

$$P = LB + TAB + SAB + FL_{20}$$

$$TFL = TAB + SAB + FL_{20}$$

$$\therefore P = LB + TFL$$

Data Sources LB, TAB & FL_{20}:

LB =	3,664,292	2021 Data from the CDC https://www.cdc.gov/nchs/data/databriefs/db442.pdf
TAB =	930,160	2020 Data from Guttmacher https://www.guttmacher.org/united-states/abortion
FL_{20} =	20,854	2020 Data from the CDC https://www.cdc.gov/nchs/data/nvsr/nvsr71/nvsr71-04.pdf

SAB: A consistent source for SAB has not been located. Here it is calculated as follows:

$$SAB = r * P$$

Where r is the rate of SAB or SABr.

Pregnancies are calculated as follows:

$$P = LB + TAB + SAB + FL_{20}$$

$$P = LB + TAB + (r * P) + FL_{20}$$

$$P - (r * P) = (LB + TAB + FL_{20})$$

$$(1-r) * P = (LB + TAB + FL_{20})$$

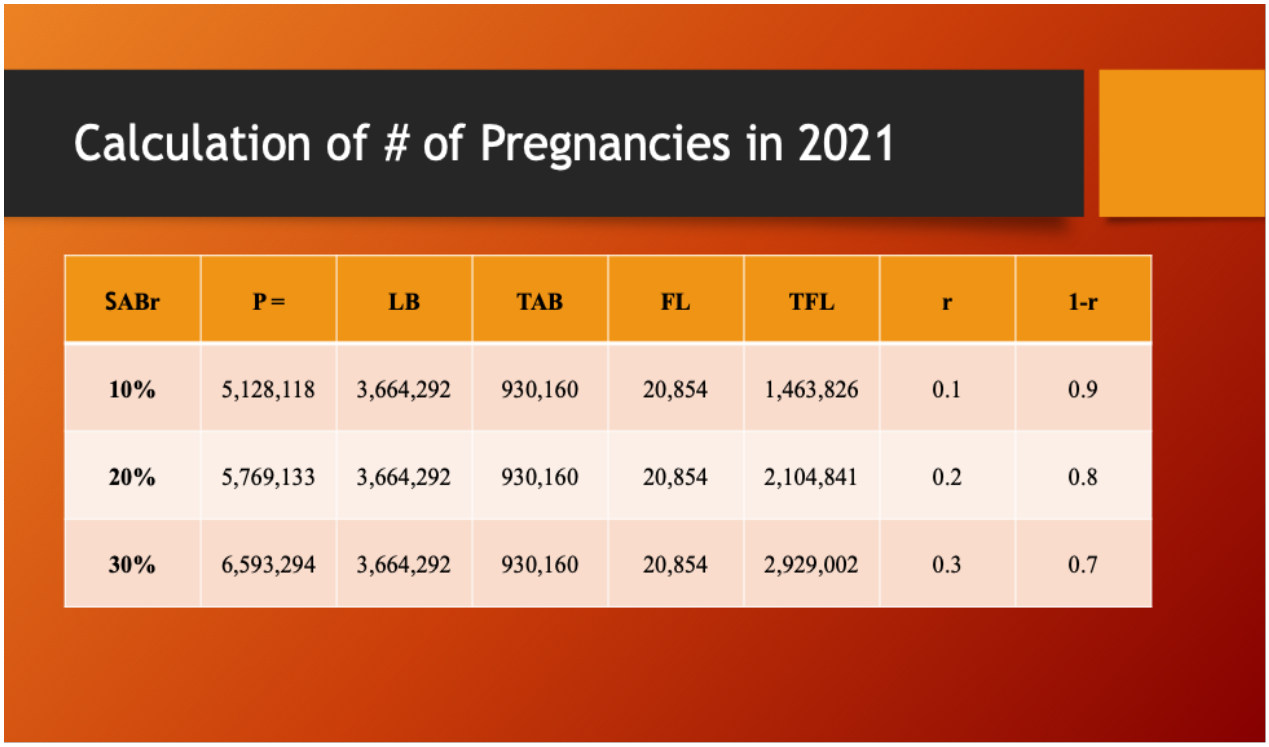
$$\therefore P = (LB + TAB + FL_{20})/(1-r)$$

Fetal loss does not occur linearly during gestation but rather is front-end loaded with most SABs occurring during the initial 20 weeks of gestation.

The first six weeks after conception are problematic with respect to recognizing pregnancy itself and loss of the conceptus. Measurement of hormone levels has disclosed a higher rate of miscarriage

than observation alone. The range of rates miscarriage has been estimated to be 10 to 30 percent of pregnancies. https://www.ncbi.nlm.nih.gov/books/NBK560521/

Chart 6: Number of Pregnancies in 2021.



SABr	P =	LB	TAB	FL	TFL	r	1-r
10%	5,128,118	3,664,292	930,160	20,854	1,463,826	0.1	0.9
20%	5,769,133	3,664,292	930,160	20,854	2,104,841	0.2	0.8
30%	6,593,294	3,664,292	930,160	20,854	2,929,002	0.3	0.7

The range of estimated pregnancies in 2021 is from 5,128,118 to 6,593,294. The range of 5,769,133 to 6,593,294 is considered to more accurately account for the first six weeks, as discussed earlier, than the 10 percent rate and will be used herein.

Estimated Pregnancies in 2021 =

5.8 to 6.6 million.

Appendix II: Estimated Number of Pregnant Women Injected with LNP/mRNA in 2021.

The 20% and 30% SABr cases will be considered further:

SABr =	**20%**	**30%**
P =	**5,769,133**	**6,593,294**

20% SABr

100% GPr*	% Vaxed	Total PW vaxed	Equal by Trimester
1 dose	0.73	4,211,467	1,403,822
2 doses	0.62	3,576,862	1,192,287
3 doses	0.20	1,153,827	384,609

50% GPr*	% Vaxed	Total PW Vaxed	Equal by Trimester
1 dose	0.37	2,105,733	694,892
2 doses	0.31	1,788,431	590,182
3 doses	0.10	576,913	190,381

25% GPr*	% Vaxed	Total PW Vaxed	Equal by Trimester
1 dose	0.18	1,052,867	350,956
2 doses	0.16	894,216	295,091
3 doses	0.05	288,457	95,191

*GPr = the rate of vaccination for the General Public as reported by (https://usafacts.org/visualizations/covid-vaccine-tracker-states/):

30% SABr

100 % GPr*	% Vaxed	Total PW vaxed	Equal by Trimester
1 dose	0.73	4,813,105	1,604,368
2 doses	0.62	4,087,842	1,362,614
3 doses	0.20	1,318,659	439,553

50 % GPr*	% Vaxed	Total PW Vaxed	Equal by Trimester
1 dose	0.37	2,406,552	794,162
2 doses	0.31	2,043,921	674,494
3 doses	0.10	659,329	217,579

25 % GPr*	% Vaxed	Total PW Vaxed	Equal by Trimester
1 dose	0.18	1,203,276	401,092
2 doses	0.16	1,021,961	340,654
3 doses	0.05	329,665	108,789

*GPr = General Public Rate

Appendix III: Estimated Number of Pregnant Women Injected in 2021 with LNP/mRNA in the First Trimester.

First Trimester		
1 Dose	20% SABs	30% SABs
100% GPr*	1,403,822	1,604,368
50% GPr*	694,892	794,162
25% GPr*	350,955	401,092
Range	350,955.56	1,604,368

2 Doses	20% SABs	30% SABs
100% GPr*	1,192,287	1,362,614
50% GPr*	590,182	674,494
25% GPr*	295,091	340,654
Range	295,091	1,362,614

*GPr = General Public Rate

Report 43: "Blood System-Related Adverse Events Following Pfizer COVID-19 mRNA Vaccination" – Barbara Gehrett, MD; Joseph Gehrett, MD; Chris Flowers, MD; and Loree Britt.

War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 1:

Hematological System Organ Class (SOC) Review of 5.3.6

SOURCE:
https://www.pmprl.org/wp-content/uploads/2022/04/vaccine_5.3.6-postmarketing-experience.pdf

5.3.6 AE REPORTING PERIOD:

"Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021."

ABBREVIATIONS:

5.3.6 : Pfizer source document

SOC : System Organ Class

AE : Adverse Event

AESI : Adverse Event of Special Interest

EUA : Emergency Use Authorization by FDA

PM : Post-Marketing

BNT162b2 : Pfizer's mRNA COVID-19 vaccine

- **Adverse Events were reported to Pfizer during a 90-day period, following the December 1, 2020, public rollout of its COVID-19 experimental "vaccine" product.**
- **In the Pfizer 5.3.6 document, these AEs were categorized by System Organ Classes (SOC) – in other words, by systems in the body.**
- **Looking at the blood components as a system, those Adverse Events reports made up 2.2% (932 individuals) of the 42,086 total trial participants with AEs identified.**
- **The hematological system includes red cells, white cells, and platelets, as well as clotting proteins.**

Diagnoses included expected and minor issues, such as bruising at the vaccination site and deeper swelling, because it was injected in the muscle. However, more serious diagnoses listed include hematoma, which is suggestive of a significant collection of blood within the deltoid muscle at the site of the injection. Other reports were triggered by vaginal bleeding, coughing up blood, vomiting blood, blood in bowel movements, bloody diarrhea, and blood in the urine.

Blood in the eye was reported, which may be of no consequence if it was only superficial bleeding caused by coughing or sneezing. But, if the bleeding was within the eye, it could cause permanent vision damage. The report does not distinguish which of these scenarios occurred.

Also noted were cases of low white cell counts. These cells protect the body from infections and cancer.

Low counts suggest some degree of altered immune response.

Blood also has clotting proteins that circulate. If there is loss or damage to one of the proteins, bleeding can occur due to inadequate clot formation. There were 53 patients reported to have low platelets numbers. Platelets are involved in starting the formation of a clot.

The questions raised by this list are how and to what extent are there disruptions of the clotting system? Are there changes to blood cells that are circulating and/or to those in the bone marrow? Is the presentation of bleeding from so many sources indicative of serious damage and, if so, of what duration? Does the low white blood cell count cause a risk of infection? Is this temporary or long lasting?

AUTHORS:
Dr Barbara Gehrett MD
Dr Joseph Gehrett MD
Dr Chris Flowers MD
Loree Britt

Post Marketing Team

09Nov22

Hematological AESIs:

AESI LATENCY:

Relevant event onset latency (n = 787):

Range from <24 hours to 33 days

median = 1 day

AESI OUTCOMES:

Relevant event outcome:
- fatal (34)
- resolved/resolving (393)
- resolved with sequelae (17)
- not resolved (267)
- unknown (371)

PFIZER CONCLUSION:

"This cumulative case review does not raise new safety issues. Surveillance will continue."

SOURCE:

https://www.pmda.go.jp/files/000244436.pdf

NOTE ON LATENCY:

The interval of time between the time a dose of drug is administered, and an effect is observed.

Post Marketing Team

Fifty percent of the adverse events reported were noted within 48 hours of Pfizer COVID-19 mRNA vaccination, but there were cases reported as long as 33 days post-injection. In the hematological group of adverse events, **there were 34 deaths and 17 cases of permanent damage.** 393 patients were categorized as "resolved or resolving," but it is unknown whether complete resolution occurred in the "resolving" group. Similarly, a large group of 267 were "not resolved" as of February 28, 2021, and 371 (34%) patients' consequences were categorized as "unknown."

5.3.6 shows a significant collection of serious diagnoses that have no certain explanation and no identification as to either cause and effect or ultimate outcome. However, in the 33 days post-injection, and mainly within the first couple of days post injection, there were serious, permanent adverse events including the ultimate serious adverse event: **death**.

Furthermore, the document concludes that these adverse events do not raise new safety issues and says surveillance will continue. Is that adequate in any system devised to assure safety of a pharmaceutical, let alone safety of one based on a novel, experimental technology?

Read Pfizer's STUNNING CONCLUSION:

4. DISCUSSION
Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

5. SUMMARY AND CONCLUSION
Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf, pp. 28-29.

Post-Marketing Team's CONCLUSION:

WHAT DOES IT TAKE?

How many serious **ADVERSE EVENTS** does it take?
How many **UNRESOLVED and UNKNOWN** outcomes does it take?
How many **DEATHS** does it take?

What does it take to **RECALL PFIZER'S UNSAFE "VACCINE"?**

Report 44: "VAERS – 76% of Vaccine-Related Miscarriages from the Past 30 Years Occurred Once Pregnant Women Started Receiving COVID-19 Vaccines" by Maria Ziminsky and Linnea Wahl, MS – Team 5.

If you are pregnant, you are more likely to lose your baby in a miscarriage if you receive a COVID-19 vaccine than if you receive measles, mumps, flu, tetanus, or any other vaccine. This and other alarming facts about risks to babies of vaccinated mothers comes from the U.S. government's own Vaccine Adverse Event Reporting System (VAERS, https://vaers.hhs.gov/about.html).

According to VAERS, from 1990 (when VAERS was established) through March 2022, miscarriages (spontaneous abortions) were reported 4,693 times by women who were vaccinated for all diseases through March 2022 (for hundreds of women, there was a reporting delay of several months). These reports include women who received one or more vaccines for diseases like measles, mumps, flu, and COVID-19. For example, among the 4,693 miscarriages that were reported, several women received vaccines for COVID-19 as well as influenza or hepatitis or another disease. So, their miscarriages were reported multiple times, once for each disease for which they were vaccinated.

To understand the effect of the COVID-19 vaccine on pregnant women, one must separate those who received multiple vaccines from those who received a single vaccine. The number of women with distinct identification (ID) numbers who miscarried after receiving a vaccine through March 2022 is 4,505. The difference between 4,693 reports of miscarriages and 4,505 distinct identification numbers is 188 (4,693 – 4,505 = 188). So, 188 women miscarried after receiving multiple vaccines, and 4,505 women miscarried after receiving a single vaccine through March 2022.

Of the thousands of miscarriages that were reported after single or multiple vaccinations for all diseases, 3,430 of those miscarriages were in women whose vaccinations, beginning in December 2020, included a COVID-19 vaccine. Of these 3,430 miscarriages, as many as 16 may have been in women who received other vaccines in addition to a COVID-19 vaccine. So, 3,414 miscarriages (3,430 - 16 = 3,414) were in women who received only the COVID-19 vaccine and no other vaccine from December 2020 through March 2022 (Fig. 1).

This means that of all the women who reported losing their babies to miscarriage after receiving a single vaccine, 76% (3,414/4,505) received only the COVID-19 vaccine. These women were vaccinated for COVID-19 from December 2020 through March 2022. So, *76% of all the vaccinations that resulted in a baby dying in miscarriage in the past 30 years or so occurred when pregnant women started receiving COVID-19 vaccines*.

Would these babies have died even if their mothers had not been vaccinated for COVID-19? Certainly that is possible, since we know that as many as 10% [https://www.acog.org/womens-health//faqs/early-pregnancy-loss] to 30% [https://www.ncbi.nlm.nih.gov/books/NBK560521/] of all

pregnant women lose their babies before 13 weeks' gestation. Later in pregnancy (after 20 weeks), the number of baby deaths, which are then stillbirths and not miscarriages, drops to less than 1% [https://www.cdc.gov/ncbddd/stillbirth/facts.html].

Unfortunately, VAERS does not indicate how far along these women were in their pregnancies when they were vaccinated for COVID-19. We can, however, get some information on the duration of a pregnancy from the descriptions entered into VAERS. For example, VAERS describes one mother's miscarriage (VAERS patient 1185268) as follows: "3/15/2021—Went to my midwife for my first prenatal visit and that's where I learned there was no heartbeat. 4 weeks along at the time of the vaccine and the heartbeat ended at 8 weeks along. This was my third pregnancy—and my first miscarriage. Estimated date of delivery was in October."

While this is one of many heartbreaking stories, it is not proof that the COVID-19 vaccine caused the miscarriage. Yet it does raise important concerns. Another source of concern is the data in Figure 1, which shows that about 61% (2,067/3,414) of the miscarriages were reported within 30 days (onset days) after the mother was vaccinated for COVID-19. For pregnant women vaccinated for other diseases, about 47% (597/1,279) of the miscarriages resulted within 30 days of vaccination. This difference is statistically significant with $p = 0.00$ using the test of two proportions.

In spite of these frightening statistics, the Centers for Disease Control and Prevention (CDC) continues to recommend that pregnant women get the COVID-19 vaccines. [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html] In the United States, these vaccines are manufactured by Moderna, Pfizer/BioNTech, and Janssen (Johnson & Johnson). Does VAERS suggest which COVID-19 vaccine is safest for an unborn baby?

Indeed, for women vaccinated for COVID-19 from December 2020 through March 2022, VAERS reports that, of the pregnant women who had miscarriages after vaccination, about 75% (2,557/3,414) received the Pfizer/BioNTech mRNA vaccine. About 21% (733/3,414) received Moderna's mRNA vaccine, and about 3% (118/3,414) received Janssen's adenovirus vaccine (Table 1).

These figures are rough; they would be more accurate if data were provided showing the total number of pregnant women vaccinated with each of the three COVID-19 vaccines and how many of that total received only a COVID-19 vaccine. In addition, the data include those who received more than one manufacturer's vaccine — for example, a woman may have received both Pfizer/BioNTech and Moderna vaccines. Still, as Team 5 has reported before, the Pfizer/BioNTech mRNA vaccine appears to be putting unborn babies at increased risk of death from miscarriage. [https://dailyclout.io/the-facts-about-pfizer-mrna-vaccine-risks-to-unborn-babies/]

These are alarming figures, and they are even more so when we understand what VAERS data represent. The U.S. government's guide to VAERS states, "'Underreporting' is one of the main limitations of passive surveillance systems, including VAERS. [https://vaers.hhs.gov/data/dataguide.html] The term underreporting refers to the fact that VAERS receives reports for only a small fraction of actual adverse events." Some researchers have found that less than 1% of adverse events are reported in VAERS. [https://digital.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system]

So, one must keep in mind that the estimated 3,414 unborn babies who died after their mothers were vaccinated against COVID-19 and had miscarriages from December 2020 through March 2022 are probably only a small fraction of the actual number of post-vaccination spontaneous abortion "adverse events." This number may actually be 100 times greater or more.

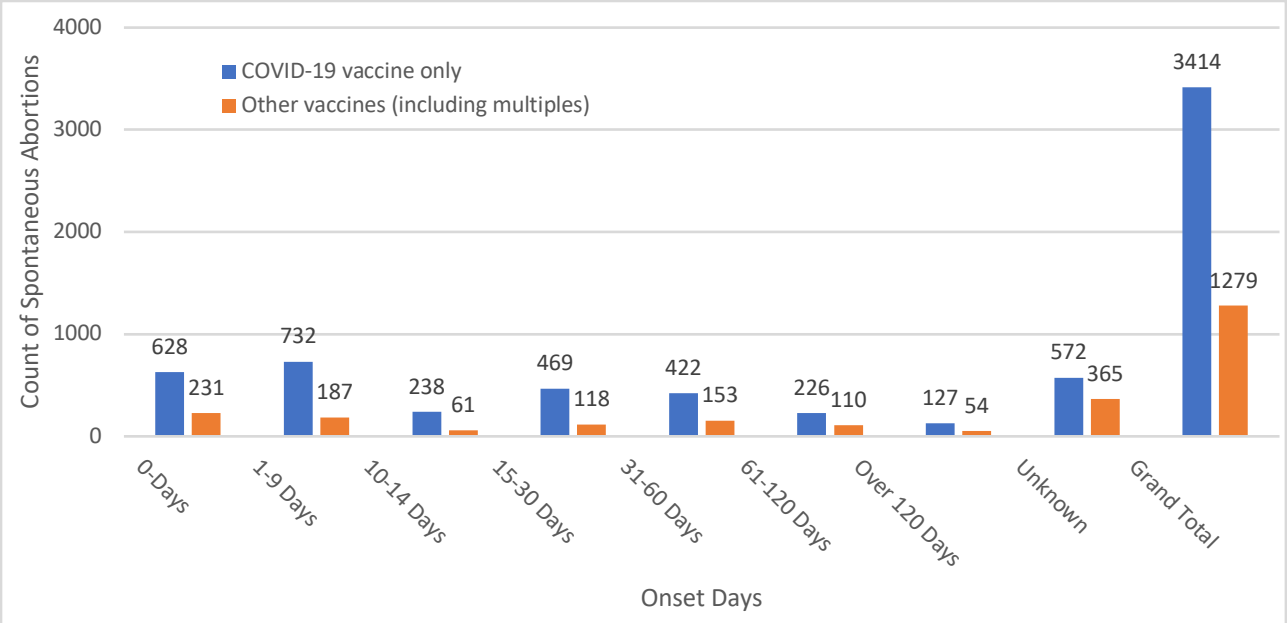
As noted, VAERS is simply a registry of passive surveillance data. Such registries are relatively inexpensive to establish and maintain, but the quality and timeliness of the data they collect are difficult to control. [https://www.ncbi.nlm.nih.gov/books/NBK11770/]

There are other limitations to data gathered in VAERS. The total count of babies who died in miscarriages after the mothers were vaccinated (4,505) varies depending on the data selection criteria, such as symptoms, vaccine manufacturer, vaccine products, and date vaccinated or reported. Indeed, if the data are sorted by "spontaneous abortion" and "death," then only 16 events are returned. Appendix A provides further detail on the query used for the data in this report.

In addition, VAERS has data integrity issues; for example, some time intervals have no data associated with them, some vaccination dates are listed as "9999" (which were included in this analysis), the type of vaccine is often missing, the system does not collect information on how old a fetus was at the time of miscarriage (i.e., how far along the woman's pregnancy was), and follow-up health records are not available (from the VAERS website: "amended [follow-up] data are not available to the public"), making it difficult to verify cause and effect. [https://vaers.hhs.gov/data.html]

At best, VAERS data can be used only as a signal that something may be wrong. *Clearly, these VAERS data send a strong signal suggesting grave danger to pregnant women and their babies from COVID-19 vaccines*. How many more babies will die in miscarriages before the U.S. Centers for Disease Control and Prevention and the Food and Drug Administration (FDA) acknowledge and act on these alarming safety signals?

Table 1. Miscarriages by COVID-19 Vaccine Manufacturers



COVID-19 vaccine manufacturer	VAERS symptom resulting in baby death	Number of cases	% of total cases
Pfizer/BioNTech	Spontaneous abortion	2,557	75
Moderna	Spontaneous abortion	733	21
Janssen	Spontaneous abortion	118	3
Unknown	Spontaneous abortion	6	<1
Total cases		**3,414**	**100**

[a] Data extracted from VAERS October 2022; data include those who received more than one manufacturer's vaccine (for example, a woman may have received both Pfizer/BioNTech and Moderna vaccines)

Fig. 1. Spontaneous Abortion Adverse Events (1990 through March 2022)[a]

[a] Data extracted from VAERS October 2022

Appendix A. VAERS Query Method

We used the following query parameters in the Vaccine Adverse Event Reporting System (VAERS) database to obtain the data discussed in this report. Fig. A1 is a screenshot of a baseline VAERS request form.

- Symptoms: Abortion Spontaneous
- VAERS ID: All
- Group By: Symptoms; Vaccine Type; Month Vaccinated; Month Reported; VAERS ID
- Show Totals: False
- Show Zero Values: Disabled
- Help: See http://wonder.cdc.gov/wonder/help/vaers.html for more information.
- Query Date: Oct 10, 2022, 5:09:33 PM

Note that the data include only spontaneous abortions (MEDDRA code = 10000234). The scope of the data includes U.S. (45%) and foreign (55%) reports.

Examples of VAERS limitations are illustrated in two screenshots of typical VAERS queries using the graphical user interface. In Fig. A2, there is no indication whether the death is to the mother or the baby. And in Fig. A3, the cause of death is noted as miscarriage, clearly referring to the miscarried baby, not the mother. For example, in the case of VAERS patient 1185268 mentioned earlier, the mother's miscarriage was recorded as "spontaneous abortion" only. Yet clearly, this miscarriage resulted in the death of a baby, even though VAERS does not classify this as a "death."

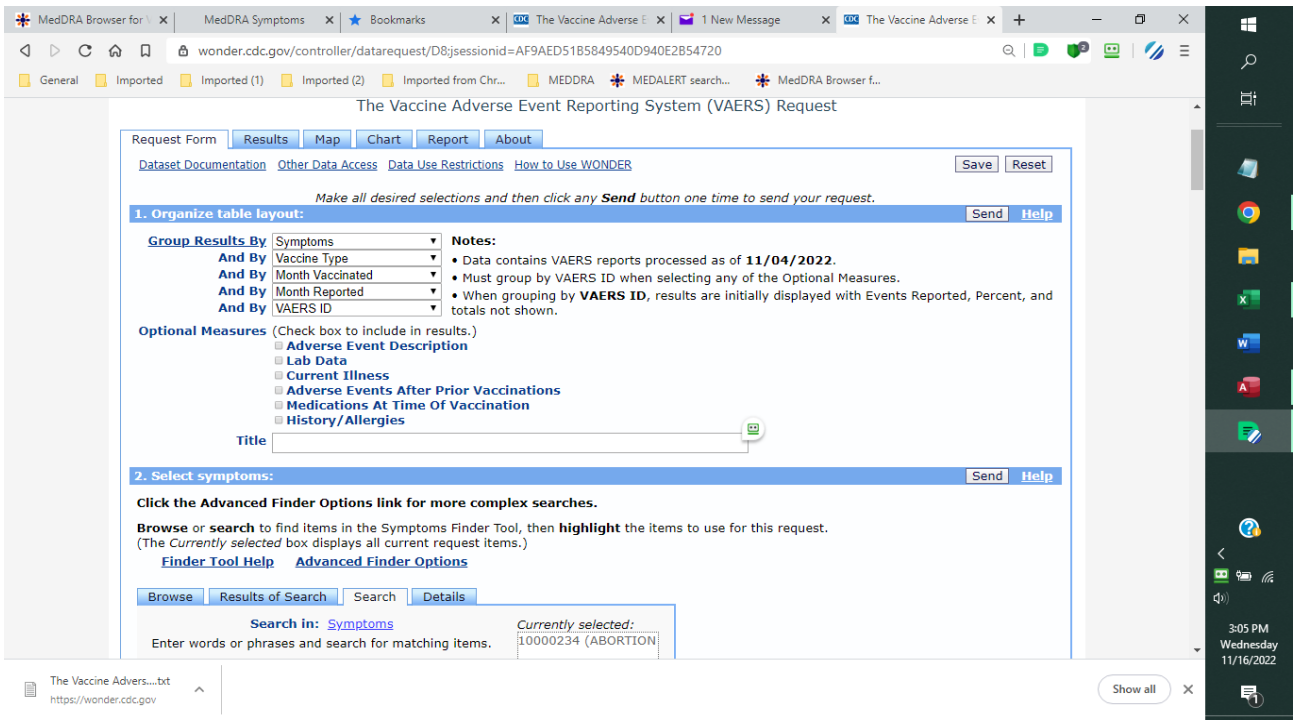


Fig. A1. Screenshot of Baseline VAERS Query

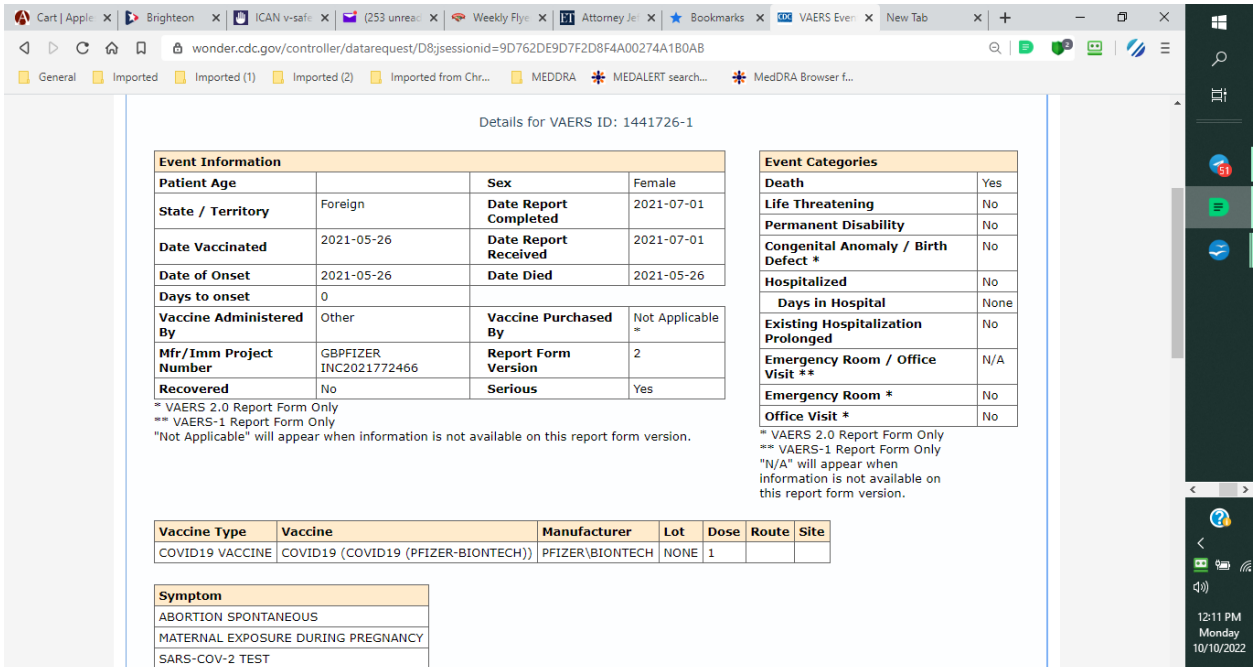


Fig. A2. Sample VAERS Query Indicating Death

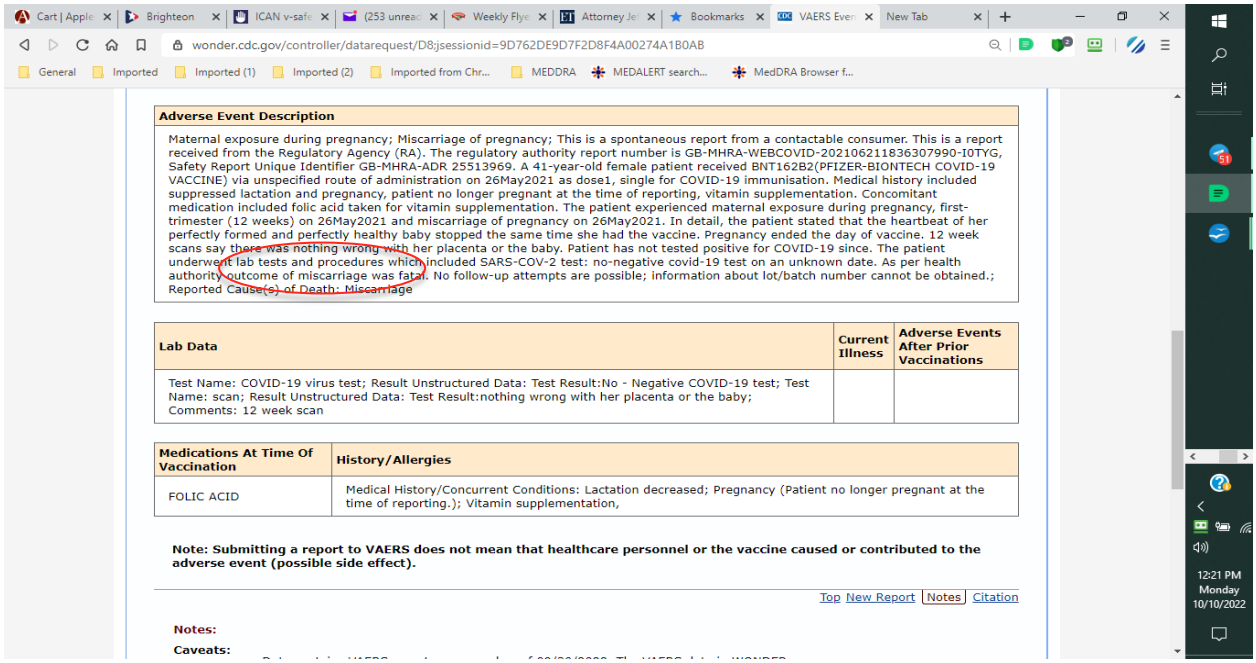


Fig. A3. Sample VAERS Query Describing Miscarriage (Spontaneous Abortion)

Report 45: "Clotting System-Related Adverse Events Following Pfizer COVID-19 mRNA Vaccination" – Barbara Gehrett, MD; Joseph Gehrett, MD; Chris Flowers, MD; and Loree Britt.

War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 2:

Thromboembolic System Organ Class (SOC) Review of 5.3.6

SOURCE:

5.3.6 AE REPORTING PERIOD:

"Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021."

ABBREVIATIONS:

5.3.6 : Pfizer source document

SOC : System Organ Class

AE : Adverse Event

AESI : Adverse Event of Special Interest

EUA : Emergency Use Authorization by FDA

PM : Post-Marketing

BNT162b2 : Pfizer's mRNA COVID-19 vaccine

THROMBUS: clot

EMBOLUS: broken off clot

- Adverse Events were reported to Pfizer during a 90-day period, following the December 1, 2020, public rollout of its COVID-19 experimental "vaccine" product.
- In the Pfizer 5.3.6 document, these AEs were categorized by System Organ Classes (SOC) – in other words, by systems in the body.
- In these first three months, post-FDA approval of the vaccine, Pfizer reported 151 cases of thromboembolic events.
- This made up 0.3% of the total Adverse Events reported, with the vast majority from Europe and North America.

The Pfizer review of these clinical reports was the compilation of the clotting events reported under diagnoses that include clotting events in arteries and veins. This includes large veins of the limbs, those clots that are carried to the lungs (pulmonary emboli) and other clots carried through the blood stream to other areas of the body.

The thromboembolic category does not include clots that cause strokes. It also does not include most other blood disorders. Both of these are reviewed independently. The thromboembolic category does include general activation of the clotting system, diffuse intravascular coagulation, which results in multi-organ damage throughout the body.

In the 151 patients there were **168 identified conditions with 165 determined to be "serious"**. There were 60 with blood clots to the lung (pulmonary embolus), and 90 events identified as blood vessel clots (primarily in veins).

The adverse events were reported from within the first 24 hours post vaccination to 28 days later, but half were reported as having started in the first four days. There were **18 deaths** with **54 cases reported as "resolved or resolving" but no further follow up to give insight on ultimate outcomes**. Pfizer reports **49 events did not resolve** and six had permanent sequelae." In **42 patients an "unknown" outcome** was reported.

Pfizer's Conclusion: **"This cumulative case review does not raise new safety issues."**

Post-Marketing Team's CONCLUSION:

How many serious **ADVERSE EVENTS, UNRESOLVED and UNKNOWN** outcomes does it take?
How many **DEATHS** does it take to **RECALL PFIZER'S UNSAFE "VACCINE"?**

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09Dec22

Report 46: "Serious Stroke Adverse Events Following Pfizer COVID-19 mRNA Vaccination" – Barbara Gehrett, MD; Joseph Gehrett, MD; Chris Flowers, MD; and Loree Britt.