# THE DANGERS OF THE COVID 19 VACCINE REPORT

# NIC and CDC Protocols ARE Causing More COVID Deaths then Covid Alone!!!

# **Prepared by Dr. Bryan Ardis**

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If You Have COVID: Why You Should NOT go to a HOSPITAL, and what you should ASK for if you are admitted to a hospital and have tested Positive for COVID! How to Prevent and Protect You and Your Loved Ones from COVID and Proven Protocols, One Medical and One Natural!

Did you know that Medical Doctors errors are the 3rd leading cause of death in America, in and out of Hospitals? Between 250k and 440k killed every year! -John Hopkins University

Study Suggests Medical Errors are now the third leading cause of death in the USA

# Now for COVID

# CDC website directs patients and doctors to NIH Website for protocol for treating COVID Patients.

Here is the link to the <u>CDC website</u>.

Click under "Management" section see the link to NIH site.

Scroll down to "clinical management and treatment" and also "severe disease", click link directing you to NIH guidelines.

NIH issues Protocol to Hospitals, on how to treat COVID patients.

# Please take a moment to read the Remdesivir protocol on NIH site.

Remdesivir is an INVESTIGATIONAL DRUG, and is NOT FDA APPROVED FOR ANYTHING

# Do you know what the side effects of this NIH recommended?

This investigational drug, which is also confirmed to NOT be FDA approved for any medical condition.

Read the Remdesivir Drug Overview

Read the Remdesivir Side Effects

Please read the 3 summaries under the warning section, 3 Chinese produced findings from clinical experiences in CHINA on COVID patients.

Please read the 3rd paragraph under the WARNING BOX on this page quoted below...

# I quote:

Cohort of 53 hospitalized patients in manufacturer's compassionate-use program:

## **Adverse effects:**

- 1. Increased hepatic enzymes (evidence of liver damage)
- 2. Diarrhea (body rejecting it), rash (body trying to sweat out drug or allergic reaction to Remdesivir)
- 3. Renal impairment (kidneys are shutting down)
- 4. Hypotension (fatally low blood pressure), reported in 60% of patients.

### Serious adverse effects:

- 1. Multiple organ dysfunction syndrome ("more than one" organ failure)
- 2. Septic shock (life threatening)

3. Acute kidney injury (kidneys fail, body retains water, lungs fill with fluid causing pulmonary edema (lungs filling with fluid) being misdiagnosed as pneumonia, patients drown to death)

4. Hypotension (fatal low blood pressure)) reported in 23% of patients in the study.

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Drug discontinued: because of adverse effects in 8% of patients. (people who had too severe side effects to continue the drug trial with Remdesivir.

Memorize this number, 8%, In this Chinese group 8% of COVID patients had such severe side effects to the drug, that the doctors **STOPPPED** the REMDESIVIR treatment to not make them sicker or kill them. Now check out this stat. As of June 20,2020, according to worldmeter.com, 7% of all treated patients in America are dying in hospitals. That number is awfully close to this 8% being poisoned by Remdesivir in the Cohort study quoted above, from drugs.com.

# **Ironic, I think NOT.**

# Check out the <u>World Meter Website</u> which is tracking all the COVID Cases numbers and deaths worldwide.

Tell me what the % is, of people who lived through treatment and the % OF THOSE THAT DIED... WHAT PERCENTAGE IS DYING AS A RESULT OF TREATMENT.

# Look it up.

Did you know that United States has more than half of all the represented deaths from COVID in the entire world...? Can you guess why... Our NIH and CDC recommended protocol is **POISONING** our citizens and if it continues so will the massacre.

Read the side effects "AGAIN" from the experiences in CHINA with this investigational drug.... Remdesivir

# I quote:

"Cohort of 53 hospitalized patients in manufacturer's compassionate-use program:

Adverse effects (e.g., increased hepatic enzymes, diarrhea, rash, renal impairment, hypotension) reported in 60% of patients.

Serious adverse effects (e.g., multiple organ dysfunction syndrome, septic shock, acute kidney injury, hypotension) reported in 23%.

Drug discontinued because of adverse effects in 8% of patients. "

To help educate all the readers of this presentation, I have copied definitions for each of the ADVERSE SIDE EFFECTS listed above, due to being treated by REMDESIVIR.

# **Definitions:**

Sourced from various reputable medical sources.

# Multiple Organ Dysfunction Syndrome:

"The multiple organ dysfunction syndrome. The most common cause of death for patients admitted to a contemporary intensive care unit (ICU) is a clinical condition that owes its existence to the development of the ICU." -John C Marshall, M.D.

# Acute Kidney Injury:

Mayo Clinic in 2018 stated "Acute kidney failure can be fatal and requires intensive treatment. However, acute kidney failure may be reversible. If you're otherwise in good health, (COVID death victims are NOT in Good health) you may recover normal or nearly normal kidney function. Jun 23, 2018"

# Septic Shock:

Medical News Today reports that- "Septic shock is a severe and potentially fatal condition that occurs when sepsis leads to life-threatening low blood pressure. Knowing how to recognize and prevent septic shock is vital. Sep 24, 2018"

# Hypotension:

Mayo Clinic States-"Low blood pressure might seem desirable, and for some people, it causes no problems. However, for many people, abnormally low blood pressure (hypotension) can cause dizziness and fainting. In severe cases, low blood pressure can be life-threatening. Apr 21, 2020"

\*\* Here are 4 serious adverse reactions to Remdesivir, each of the 4 serious adverse reactions to the Drug from the studies are potentially FATAL!\*\*

### **Report in Science Magazine April 2020**

Two quotes from the Science Magazine article linked above should sound alarm:

Multiple battlefields (paragraph).

"The worldwide fears of ventilator shortages for failing lungs have received plenty of attention. Not so a scramble for another type of equipment: dialysis machines. "If these folks are not dying of lung failure, they're dying of renal failure," says neurologist Jennifer Frontera of New York University's Langone Medical Center, which has treated thousands of COVID-19 patients. Her hospital is developing a dialysis protocol with different machines to support additional patients. The need for dialysis may be because the kidneys, abundantly endowed with ACE2 receptors, present another viral target. According to one preprint, 27% of 85 hospitalized patients in Wuhan had kidney failure. Another reported that 59% of nearly 200 hospitalized COVID-19 patients in China's Hubei and Sichuan provinces had protein in their urine, and 44% had blood; both suggest kidney damage. Those with acute kidney injury (AKI), were more than five times as likely to die as COVID-19 patients without it, the same Chinese preprint reported."

### Crazy right...

### **IMPORTANT!**

1. DID YOU READ THAT?!!!!!! Reported by China..." Those with acute kidney injury (AKI), were more than five times as likely to die as COVID-19 patients without it "!

2. Stay with me... Those with Acute Kidney Injury are 5 X more likely to DIE than COVID patients without Acute Kidney Injury!

3. Remdesivir: CAUSES "ACUTE KIDNEY INJURY IN 23% of ALL patients, per the drug makers cohort study!!!! quoted again from drugs.com "Serious adverse effects (e.g., multiple organ dysfunction syndrome, septic shock, ACUTE KIDNEY INJURY, hypotension) reported in 23%;"

# Logical Conclusion:

If the NIH and CDC are going to enforce Hospitals to use Remdesivir as the go to drug for COVID patients, (remember it isn't even an FDA approved drug for anything). And Remdesivir Causes Acute Kidney Failure in COVID patients as reported in China's Cohort study, and COVID patients who experience ACUTE KIDNEY INJURY COVID victims are 5X more likely to die than COVID infected patients alone... Would it be logical and I scream, WOULD IT NOT BE LOGICAL TO "NOT" GIVE COVID POSTIVE PATIENTS A DRUG THAT IS PROVEN TO CAUSE ACUTE KIDNEY INJURY?!...THE ONE SIDE EFFECT OR ORGAN INJURY THAT ENSURES THE LIKELIHOOD OF YOU DYING GOES UP BY 5 times!!!

Anyone else see the madness in pumping millions of people with this NON-FDA APPROVED, ACUTE KIDNEY INJURY-ing AND DEATH CAUSING "INVESTIGATIONAL" DRUG, REMDESIVIR.

# It is MADNESS...

Why would our government health agencies push this proven poison known as Remdesivir? Why... it doesn't make any sense.

Second quote from Science Magazines article cited above: "The intestines are not the end of the disease's march through the body.

"For example, up to one-third of hospitalized patients develop conjunctivitis pink, watery eyes—although it's not clear that the virus directly invades the eye. Other reports suggest liver damage: More than half of COVID-19 patients hospitalized in two Chinese centers had elevated levels of enzymes indicating injury to the liver or bile ducts. But several experts told Science that direct viral invasion isn't likely the culprit.

# They say other events in a failing body, like drugs or an immune system in overdrive, are more likely driving the liver damage."

## **IMPORTANT!**

1. All along, the treated COVID patients in hospitals are not only experiencing Acute Kidney Injury, but also LIVER DAMAGE!

2. Remember the Serious Adverse Reactions to Remdesivir (the ONLY drug these hospitals are being told to treat COVID patients with!)

I quote again... "Serious adverse effects (e.g., MULTIPLE ORGAN DYSFUNCTION, septic shock, ACUTE KIDNEY INJURY, hypotension) reported in 23%;"

3. Remember the definition of MULTIPLE ORGAN DYSFUNCTION SYNDROME (now we have liver and kidney injury being reported by hospitals) here is the definition from John C. Marshall.... "The multiple organ dysfunction syndrome. The most common cause of death for patients admitted to a contemporary intensive care unit (ICU) is a clinical condition that owes its existence to the development of the ICU."

4. Hospital treatments including Remdesivir, are CAUSING Multiple Organ Dysfunction Syndrome in COVID patients, and Multiple Organ Dysfunction Syndrome is the "The most common cause of death for patients admitted to a contemporary intensive care unit (ICU)"

## **Conclusion:**

NIH hospital protocols using Remdesivir is causing COVID patients to experience Acute Kidney Injury and Multiple Organ Dysfunction Syndrome which is Literally Killing COVID 19 Patients 5 times more often than those suffering with COVID alone!

### Stop the DEADLY NON-FDA-APPROVED PROTOCOL!

(\* this report was created in June 2020, as of 10/2020, FDA has been pressured and has approved Remdesivir, after 8 months of killing thousands of American citizens)

# Why is the NIH and CDC telling Hospitals to use Remdesivir?

Because of a study on Ebola in Africa, four years ago, in which the Remdesivir trial group was taken OFF Remdesivir halfway through the trial and put on different medications being used in the study, BECAUSE Remdesivir had the HIGHEST MORTALITY

RATES (DEATH RATE) of ALL 4 trial drugs!!!

Rear the study and see for yourself: <u>A Randomized</u>, <u>Controlled Trial Of Ebola Virus</u> <u>Therapeutics</u>

Check out Figure 1-4 in the Mortality section.

Remdesivir had a higher percentage of death than ALL the other 3 trial medications for the Ebola Virus, in first 28 days of treatment.

Follow these Study Results with the summaries quoted on drugs.com of Remdesivir side effects and in my opinion, you have a protocol of death, if you treat any COVID patients with Remdesivir.

Now on to the next PROBLEM, I have with the Hospital protocols for COVID. WHY ARE THEY PRESCRIBING MULTIPLE ANTIBIOTICS TO COVID PATIENTS IF ANTIBIOTICS ONLY KILL BACTERIA? EVERY HUMAN BEING KNOWS COVID IS AN INFECTION OF A VIRUS, AND EVERY DOCTOR AND HOSPITAL KNOWS THAT ANTIBIOTICS DON'T TREAT OR KILL ANY VIRUSES, THEY ONLY TREAT BACTERIA INFECTIONS!

A few articles from the trusted WebMD website and statements from the CDC on use of antibiotics when you someone has a virus not a bacteria infection.

Read this WebMD article titled: <u>Why you SHOULD NOT be prescribed antibiotics when</u> you have a viral infection.

"Antibiotics only cure certain infections due to bacteria -- and if taken carelessly, you may get more serious health problems than you bargained for. With any illness, it is critical to address the underlying cause, whether it's bacterial or viral. Antibiotics will not kill...viruses." Why in the WORLD are we adding ANTIBIOTICS to try and TREAT COVID, a known disease caused by a VIRUS?

So now we are killing people who have COVID, with drug that is NOT FDA Approved drug (Remdesivir) and putting unwarranted bacterial drugs, called antibiotics (that have their own side effects which some include Acute Kidney Injury as a side effect) into people with confirmed virus infections. Aren't we smarter than that? Appears not.

Even the CDC has said that giving Antibiotics to people with Viral Infections is Dangerous!" <u>Check out this article in Medical News Today titled: Taking Antibiotics for</u> <u>Viral Infections Can Do More Harm Than Good, CDC.</u>

"According to the US Centers for Disease Control and Prevention, where children are concerned, antibiotics are the most common cause of emergency department visits for adverse drug events. Rest, fluids, and over-the-counter medication is the preferred option for treating a virus, says the CDC. Colds and many other infections of the upper respiratory tract, plus some ear infections, are not caused by bacteria, but by viruses.

Antibiotics do not work against viruses, only bacteria, yet although CDC efforts have led to fewer children receiving unnecessary antibiotics in recent years, too many are too often being given antibiotics for colds and other viral infections."

# The Truth about Hydroxychloroquine and COVID 19

The Real Research Proven Benefits of Hydroxychloroquine (HCQ) and the STUDIES of its use with COVID patients. This link will show you the 66 medical research studies as of 05/2021 of HCQ use with COVID patients. Over 50 show positive results and almost 30 of these recent and current studies are PEER REVIEWED.

Study the results and proof for yourself here.

# C19 Study

There is even more hope however...

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Go with what is safe proven and use medications when warranted that are FDA approved and proven effective against ANY viruses! First if you are going to do any medical treatment whatsoever use FDA approved medications. I personally would recommend Dr Richard Bartlett MD's, COVID PROTOCOL which he combines with Zinc supplementation and has experienced 100% COVID cure like ALL his patients in Odessa, TX

You can watch Dr Bartlett's Interview on YouTube explaining his protocol and success with COVID patients, type this title of the interview in YouTubes Search engine.

# Dr. Richard Bartlett | ACWT Interview 7.2.20

Here is his paper submitted to Ted Cruz and delivered to the White House last week.

# Dr. Richard Bartlett Paper to Ted Cruz

Be sure to check out the links below in his paper that reference how zinc and other nutrients help fight viruses including COVID-19

Respiratory Therapeutics Week. (2020, May 11). Coronavirus - COVID-19; The LEAD COVID-19 trial: Low-risk, early aspirin, and vitamin d to reduce COVID-19 hospitalizations.

Skalny, A., Rink, L., Ajsuvakova, O., Aschner, M., Gritsenko, V., Alekseenko, S., Svistunov, A., Petrakis, D., Spandidos, D., Aaseth, J., Tsatsakis, A., & Tinkov, A. (2020).

Zinc and respiratory tract infections: <u>Perspectives for COVID-19 (Review)</u>. International <u>Journal of Molecular Medicine</u>, 46(1). Kumar, A., Kubota, Y., Chernov, M., & Kasuya, H. (2020).

Potential role of zinc supplementation in prophylaxis and treatment of COVID-19. Medical Hypotheses, 144, 109848.

# Dr Ardis' thoughts on Dr. Richard Bartlett's Protocol.

1. I believe his protocol is safe and he is using ONLY FDA approved

medications.

2. He is NOT using investigational drugs (Remdesivir) that is proving to kill hundreds of thousands of people in hospitals.

3. I do not agree with his use of Antibiotics at all, but he is suggesting it short term, which is better, and if you are concerned enough about your health that you want to follow a medical protocol and have COVID, I would say 100% of the time.

Demand Richard Bartlett's Protocol, print his paper and give it to your primary care doctor. DO NOT GO TO THE HOSPITAL!

4. In my opinion the zinc supplementation is killing the virus, not the steroid, steroids don't kill infections, just as antibiotics don't kill viruses. However, Zinc for decades has proven to kill viruses and stop viruses from replicating!

Know your rights as a <u>Patient or Patient Advocate in Hospitals</u>, It can and will save your life or loved one's life!

# **DR ARDIS'S RECOMMENDATIONS**

FOR ALL THOSE WHO CHOOSE TO TAKE A MORE NATURAL APPROACH TO BOOSTING YOUR IMMUNE SYSTEM AND HANDLING ANY INFECTION INCLUDING COVID, WITHOUT MEDICATIONS!

# Vitamin C (ascorbic acid): (preventative 3,000 mg daily/ with COVID 10,000 mg daily)

has been shown for decades to have antiviral and antibacterial benefits. It increases our White Blood Cell count (our natural antibodies), and it specifically increases INTERFERON levels, which is a chemical factor our body makes that fights viral infections specifically! At specific doses our immune system can effectively handle the removal of any virus.

### Here is some evidence.

J. SCOTT, "ON THE BIOCHEMICAL SIMILARITIES OF ASCORBIC ACID AND INTERFERON," J THEOR BIOL 98 (1982): 235-8.

C. HUNT ET AL., "THE CLINICAL EFFECTS OF VITAMIN C SUPPLEMENTATION IN ELDERLY HOSPITALIZED PATIENTS WITH ACUTE RESPIRATORY INFECTIONS," INT J

VIT NUTR RES 64 (1994):212-9.

H. BAUR AND H. STAUB. "TREATMENT OF HEPATITIS WITH INFUSIONS OF ASCORBIC ACID: COMPARISON WITH OTHER THERAPIES," JAMA 156 (1954):565.

E. GINTER, "OPTIMUM INTAKE OF VITAMIN C FOR THE HUMAN ORGANISM," NUTR HEALTH 1 (1982): 66-77.

# Zinc: (50mg daily/ with COVID 100mg Daily, I prefer zinc gluconate)

inhibits the growth of many viruses! A deficiency of zinc in the body causes suppression of the immune system by reducing white blood cell count, reducing T cell count, lowers thymus hormones that keep immunity strong. The immune systems strength immediately improves upon supplementation.

### Here is some evidence.

J.W. HADDEN, "THE TREATMENT OF ZINC DEFICIENCY IS AN IMMUNOTHERAPY," INT J IMMUNOPHARMAC 17 (1995): 697-701.

M. DARDENNE, J. PLEAU, B. NABARRA, ET AL., "CONTRIBUTION OF ZINC AND OTHER METALS TO THE BIOLOGICAL ACTIVITY OF THE SERUM THYMIC FACTOR," PROC NATL ACAD SCI 79 (1982): 5370-3.

E. KATZ AND E. MARGALITH, "INHIBITION OF VACCINIA VIRUS MATURATION BY ZINC CHLORIDE," ANTIMICROBIAL AGENTS CHEMOTHERAPY 19 (1981): 213-7.

M. GERSHWIN, R. BEACH, AND L. HURLEY, "TRACE METALS, AGING, AND IMMUNITY," J AM GER SOC 31 (1983): 374-8.

\*PLUS, RICHARD BARTLETT'S TWO CITED ZINC STUDIES ABOVE IN HIS PROTOCOL

# Selenium: (Preventative 200mcg daily/ with COVID 400mcg daily)

deficiency has been shown to inhibit resistance to infection because of impaired white blood cell and thymus function! Low in selenium, you cannot and will not be able to prevent the acquiring of the COVID-19 virus and its onslaught of symptoms. Selenium supplemented stimulates increase in white blood cells and increases immediately thymus function, thus empowering your immunity!

# Here is some evidence.

L. KIREMIDJIAN; SCHUMACHER AND G. STOTSKY, "SELENIUM AND IMMUNE RESPONSES," ENVIRONMENTAL RES 42 (1987): 277-303.

M. ROY, "SUPPLEMENTATION WITH SELENIUM AND HUMAN IMMUNE CELL FUNCTIONS 1: EFFECT ON LYMPHOCYTE PROLIFERATION AND INTERLEUKIN 2 RECEPTOR EXPRESSIONS," BIOL TRACE ELEM RES 41 (1994):103-14. ECHINACEA: (PREVENTATIVE 900MG DAILY, WITH COVID 1800MG DAILY) HERBAL CAPSULES PROVIDE THE MOST POWERFUL PREVENTATIVE AND ACTIVE

IMMUNITY AGAINST ALL VIRUSES INCLUDING THE CORONA VIRUS. EVERY ASPECT OF OUR INTERNAL IMMUNE SYSTEMS ARE ENHANCED BY ECHINACEA! IT MUST BE UTILIZED NOW TO HELP PROTECT ALL OF US. R. BAUER AND H. WAGNER, "ECHINACEA SPECIES AS POTENTIAL IMMUNOSTIMULATORY DRUGS," ECON MED PLANT RES 5 (1991): 253-321.

M. ERHARD ET AL., "EFFECT OF ECHINACEA ACONITUM, LACHESIS, AND APIS EXTRACTSM AND THEIR COMBINATIONS ON PHAGOCYTOSIS OF HUMAN GRANULOCYTES," PHYTOTHER RES 8 (1994): 14-7

Your fear should be greatly reduced I hope after doing through ALL this information I have provided. I wish all of you and your loved ones the healthiest of lives and the least amount of stress and worry imaginable. There are better alternative approaches to beat and have victory over COVID-19.

### We NO LONGER NEED TO BE CRIPPLED BY FEAR.

I plead with all of you to learn as much as you can about the nutritional protocol, I listed above to support your own bodies defenses against ALL viruses forever into the future. Our Natural Killer cells in our bodies are 99.997 percent effective at clearing and handling and healing from the COVID 19 virus and all other viruses! Before ever considering vaccine please look at the links I provide in the next section.

# THE COVID MIRACLE DRUG: IVERMECTIN FLCCC.NET

# IVERMECTIN is the GREATEST PROVEN DRUG TO PREVENT AND BEAT COVID19!

With over 30 studies in 18 countries just in 2020 alone. To learn more please go to FLCCC.NET, if you haven't seen Dr. Pierre Kory's testimony before the senate in Washington pleading for the NIH to look at all the research, I would recommend you watch it! Ivermectin has been proven to STOP 100% of transmission of Covid 19 in less than 48 hours! None of the Covid 19 vaccines even state on their fact sheets that they protect you from getting covid and they don't stop transmission of Covid.

I beg you to learn more about Ivermectin. If your MD won't prescribe it to you, then search the FLCCC.net website, they have directories around the world and US of MD's who will write you a prescription. Check it out!

# **COVID 19 VACCINES**

# What should you know about COVID 19 Vaccines?

An October 22, 2020, FDA internal report including Serious Adverse Events expected from the coming COVID-19 vaccines. In this presentation on <u>slide #16</u> the FDA listed 110 possible diseases and neurological conditions and deaths, listed as expected Side Effects. These are expected to be reported when COVID-19 Vaccines become available in December 2020. This FDA report was published in October two months before the Emergency Use Authorization was published by the FDA, which includes NONE of the Serious Listed Side Effects listed in their internal report in October. Why would they exclude these expected horrible side effects in December, that they knew were to be expected in the October report. Anyone have a problem with this? I do. Look at Slide 16...

2. Fact Sheets on FDA website for each Vaccine being administered state the vaccine is NOT FDA approved to prevent COVID 19. This is stated in the first paragraph of the EUA Fact Sheet. Check them out <u>here</u>, also look at the list of side effects possible from the Fact Sheet, and ask yourself, why did the FDA exclude in these Fact Sheets supposedly to be shared with citizens getting the COVID 19 vaccines, why did they exclude the listed Disease and Death side effects found on slide 16 from the FDA report in October, why are they hiding this from the public, this is conspiring to hide info.

3. What Serious Adverse Events are being reported to the government directly caused by COVID 19 Vaccines. Thousands of deaths and Serious life-threatening injuries reports to vaers.hhs.gov. You can download the updated list daily.

4. Harvard in 2010 published a report that less than 1% of ALL injuries from ALL vaccines are reported to VAERS. There have already been over 2000 deaths contributed and reported due to the COVID 19 Vaccines. If that represented less than 1 % reported to VAERS, than that means there has been possibly over 200,000 deaths due to the COVID vaccine alone. That is if you trust Harvard's data.

5. Everyone I recommend watching this interview with Dr. Lee Merritt MD, licensed 30year spinal surgeon who discusses why she promotes the use of Smallpox Vaccines and why she does NOT recommend COVID 19 Vaccines, and her medical and scientific use of masks. Here is the <u>link</u>.

# **COVID-19 VACCINE INJURIES -THE NUMBERS**

# **Dr. Bryan Ardis**

# Updated 5/17/2021

VAERS Data 5/7/2021, Less than 1% is being reported. Per Harvard's 2010 Published review of the Vaccine Adverse Events Reporting System of the Dept. of Health and Human Services. Included in this report is the Harvard 2010 published review of the

government vaccine injury reporting system, please reference this link to the <u>Harvard</u> <u>Report</u>.

First 150 days of Vaccinating Americans. (Please reference slide 16 from FDA's report in October 2020, link is in my Covid report), they knew ALL of these were going to happen before they started pushing the vaccines in December 2020.

Per the <u>October Report</u> slide 16 has 4 blood clotting issues listed as side effects.

J&J reports in the media that 6 rare blood clots were enough to pause the J&J vaccine use.

Numbers of reported Blood Clot related injuries to VAERS for all Vaccines is 3,272 means more likely 327,200 have occurred.

Reported so far Pfizer (1,218 blood clot reports), Moderna 1,034 blood clot reports, and J &J (1,000 blood clot reports) Blood clot disorders reported total per VAERS.HHS.GOV: 3,272 (per Harvard it would be more like 327,200 have happened. 3,272 would be only 1% of actual events)

Why has the Moderna and Pfizer vaccine distribution remained un-paused? All readers should do a search into which of these other three vaccines, Anthony Fauci's Organization (NIAID) owns portions of the patent on one of these vaccines and he personally receives royalties on. It is NOT the J&J vaccine by the way.

# DR. BRYAN ARDIS - DANGERS OF THE COVID 19 VACCINE REPORT

## Some Numbers Listed as: Reported and (Actual) Deaths 7/16/2021.

VAERS Data Reported Injuries: 7/16/2021

Blood Clot related injuries: 7,633 (763,300)

GUILLAIN-BARRE: 429 (42,900)

PREGNANT WOMEN INJURED and/or MISCARRIED 2,488 (248,800)

BELL'S PALSY 2,428 (242,800)

NOT EVEN ON THE LIST FROM OCT SLIDE 16 SERIOUS ADVERSE EVENTS: 17,190 (1,719,000 EVENTS, FROM THE FDA OCT REPORT SLIDE 16)

ANAPHYLACTIC SHOCK: 117,379, (11,737,900) THIS IS OVER 11 MILLION PEOPLE, ONLY 2 MILLION DIED WORLDWIDE SUPPOSEDLY.

DISGUSTING. THIS IS JUST THE AMERICAN REPORTS.

TOTAL ADVERSE EVENTS REPORTED: 192,954 (19,295,400) ADVERSE EVENTS.

Now why are we telling people to get COVID 19 Shots?

626,769 Americans supposedly died from COVID as of 7/26/2021.

Check this out...

Deaths reported from Covid 19 Vaccines: 11,405 equals 1,140,500 probable deaths from COVID 19 Vaccines (16% Died within 24 hours of shots; 24% died in less than 48 hours) 21% due to Heart Attacks and Strokes

For up-to-date VAERS underreporting data, sign up at <u>Children's Health Defense</u>. They provide weekly email updates.

To access data on COVID injuries reported go to <u>VAERS.HHS.GOV</u>! To get the latest updates from The Dr. Ardis Show please click the links below to subscribe!



VOKAL



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# **ADDITIONAL RESOURCES**

Grant Final Report Grant ID: R18 HS 017045

# Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)

Inclusive dates: 12/01/07 - 09/30/10

**Principal Investigator**: Lazarus, Ross, MBBS, MPH, MMed, GDCompSci

**Team members:** Michael Klompas, MD, MPH

**Performing Organization:** Harvard Pilgrim Health Care, Inc.

**Project Officer:** Steve Bernstein

Submitted to: The Agency for Healthcare Research and Quality (AHRQ) U.S. Department of Health and Human Services 540 Gaither Road Rockville, MD 20850 www.ahrq.gov

# Abstract

**Purpose:** To develop and disseminate HIT evidence and evidence-based tools to improve healthcare decision making through the use of integrated data and knowledge management.

**Scope:** To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs.

**Methods:** Electronic medical records available from all ambulatory care encounters in a large multi-specialty practice were used. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions were evaluated for values suggestive of an adverse event.

**Results:** Restructuring at CDC and consequent delays in terms of decision making have made it challenging despite best efforts to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial and comparison of ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. However, Preliminary data were collected and analyzed and this initiative has been presented at a number of national symposia.

Key Words: electronic health records, vaccinations, adverse event reporting

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# **Final Report**

# Purpose

This research project was funded to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS), via the following aims:

**Aim 1.** Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration.

**Aim 2.** Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS).

**Aim 3.** Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

**Aim 4.** Distribute documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems.

# Scope

Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP:VAERS project developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and made attempts at formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data were available from Epic System's Certification Commission for Health Information Technology-certified EpicCare system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically.

Clinicians in-basket messaging was designed to provide a preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish to send a report to VAERS. Clinicians would then have the option of adding free-text comments to prepopulated VAERS reports or to document their decision not to send a report. The CDC's Public Health Information Network Messaging System (PHIN-MS) software was installed within the facilities so that the approved reports could be securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

# Methods

The goal of Aim 1: Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration, and Aim 2: Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS), was to construct the below flow of data in order to support the first two Aims:



Existing and functioning ESP components are shown on the left, and Aims 1 and 2 on the right. ESP:VAERS flags every vaccinated patient, and prospectively accumulate that patient's diagnostic codes, laboratory tests, allergy lists, vital signs, and medication prescriptions. A main component of Aim 1 was to *Develop AE criteria to assess these parameters for new or abnormal values that might be suggestive of an adverse effect*. A reporting protocol & corresponding algorithms were developed to detect potential adverse event cases using diagnostic codes, and methods were tested to identify prescriptions or abnormal laboratory values that might be suggestive of an adverse effect. These algorithms were designed to seek both expected and unexpected adverse effects.

This reporting protocol was approved by both internal & external partners. We initially prepared a draft document describing the elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events, including those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination) and those to be reported at the discretion and with additional information from the attending physician through a feedback mechanism. The draft was then widely circulated as an initial / working draft for comment by relevant staff in the CDC and among our clinical colleagues at Atrius. In addition to review by the internal CDC Brighton Collaboration liaison, this protocol has also received review & comment via the CDC's Clinical Immunization Safety Assessment (CISA) Network.

The goal of Aim 2 was the *Development of HL7 messages code for ESP:VAERS to ensure secure transmission to CDC via PHIN-MS*. The HL7 specification describing the elements for an electronic message to be submitted to Constella, the consultants engaged by CDC for this project was implemented. Synthetic and real test data was been generated and transmitted between Harvard and Constella. However, real data transmissions of non-physician approved reports to the CDC was unable to commence, as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

The goal of Aim 3 was to Comprehensively evaluate ESP: VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

We had initially planned to evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC's Immunization Safety Office and eight large managed care organizations. Through a randomized trial, we would also test the hypothesis that the combination of secure, computer-assisted, clinicianapproved, adverse event detection, and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system; however, due to restructuring at CDC and consequent delays in terms of decision making, it became impossible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, and compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. Therefore, the components under this particular Aim were not achieved.

Aim 4 Distribution of documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems has been successfully completed. Functioning source code is available to share under an approved open source license. ESP:VAERS source code is available as part of the ESP source code distribution. It is licensed under the LGPL, an open source license compatible with commercial use. We have added the ESP:VAERS code, HL7 and other specifications and documentation to the existing ESP web documentation and distribution resource center http://esphealth.org, specifically, the Subversion repository available at: http://esphealth.org/trac/ESP/wiki/ESPVAERS.

# Results

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

In addition, ESP:VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

### Inclusion of AHRQ Priority Populations

The focus of our project was the Atrius Health (formerly HealthOne) provider & patient community. This community serves several AHRQ inclusion populations, specifically low-income and minority populations in primarily urban settings.

Atruis currently employs approximately 700 physicians to serve 500,000 patients at more than 18 office sites spread throughout the greater Metropolitan Boston area. The majority of Atruis physicians are primary care internal medicine physicians or pediatricians but the network also includes physicians from every major specialty.

The entire adult and pediatric population served by Atruis was included in our adverse event surveillance system (ESP:VAERS). Atruis serves a full spectrum of patients that reflects the broad diversity of Eastern Massachusetts. A recent analysis suggests that the population served by Atruis is 56% female, 16.6% African American, 4% Hispanic. The prevalence of type 2 diabetes in the adult population is 5.7%. About a quarter of the Atruis population is under age 18.

# **List of Publications and Products**

ESP:VAERS [source code available as part of the ESP source code distribution]. Licensed under the GNU Lesser General Public License (LGPL), an open source license compatible with commercial use. Freely available under an approved open source license at: http://esphealth.org.

Lazarus, R, Klompas M, Hou X, Campion FX, Dunn J, Platt R. Automated Electronic Detection & Reporting of Adverse Events Following Vaccination: ESP:VAERS. The CDC Vaccine Safety Datalink (VSD) Annual Meeting. Atlanta, GA; April, 2008.

Lazarus R, Klompas M Automated vaccine adverse event detection and reporting from electronic medical records. CDC Public Health Informatics Network (PHIN) Conference August 27, 2008.

Klompas M, Lazarus R ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 17th.

Lazarus R, Klompas M, Kruskal B, Platt R Temporal patterns of fever following immunization in ambulatory care data identified by ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Linder J, Klompas M, Cass B, et al. Spontaneous Electronic Adverse Event Reporting: Perspectives from Clinicians, EHR Vendors, Biopharma, and the FDA. Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

#### India - people\_vaccinated\_per\_hundred vs new\_deaths\_per\_million Source: https://covid.ourworldindata.org/data/owid-covid-data.xlsx people\_vaccinated\_per\_hundred - new deaths per million 2.0 10 8 -1.5 6 -1.0 Δ 0.5 2 -0.0 0 2020-01-30 2020-02-09 11-05 12-05 2020-02-19 2020-02-29 2020-03-10 2020-03-20 2020-03-30 6 2020-04-29 2020-09-26 2020-10-06 2020-10-16 2020-10-26 11-15 11-25 12-15 9 \$ 2020-05-09 2020-05-19 2020-05-29 2020-06-08 2020-06-18 2020-06-28 2020-07-08 2020-09-06 2020-09-16 -03-15 -03-25 2020-07-18 2020-07-28 Ş -02-23 2020-08-07 2020-08-27 2020-08-1 0 -02 ę 2020-04 9 9 \$ 9 2020-04 2021-01 ę 2020-1 2020-1 2020-1 2020-1 2020-1 2020-1 2021 2021 2021 2021 2021 202 202 202 202

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## FACT SHEET FOR RECIPIENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

### WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

### WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

### WHAT IS THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

# WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

### WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

### WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

### WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

### HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

### HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

### WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

### WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

### WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

### WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?

It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

### ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?

Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

### CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

### WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

### WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?

No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

### **KEEP YOUR VACCINATION CARD**

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

### **ADDITIONAL INFORMATION**

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA
	(1-866-663-3762)

### **HOW CAN I LEARN MORE?**

- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at <u>https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-</u> regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

### WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: <u>https://www.cdc.gov/vaccines/programs/iis/about.html</u>.

### WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit <u>www.hrsa.gov/cicp/</u> or call 1-855-266-2427.

### WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDAapproved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

## FACT SHEET FOR RECIPIENTS AND CAREGIVERS

## EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see <u>www.cvdvaccine.com</u>.

### WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

### WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

### WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

# WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

# WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

# WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

# WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

# HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

## HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

### WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

## WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

### WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.
Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Complete and submit reports to VAERS online at

<u>https://vaers.hhs.gov/reportevent.html</u>. For further assistance with reporting to VAERS call 1-800-822-7967. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

### WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?

It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

### ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?

Currently, there is no approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

### CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

### WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

### WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?

No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

### **KEEP YOUR VACCINATION CARD**

When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

### ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number	
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)	

### HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at <a href="https://www.cdc.gov/coronavirus/2019-ncov/index.html">https://www.cdc.gov/coronavirus/2019-ncov/index.html</a>.
- Visit FDA at <u>https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization</u>.
- Contact your local or state public health department.

### WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: <u>https://www.cdc.gov/vaccines/programs/iis/about.html</u>.

### WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

### WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).



Manufactured by Pfizer Inc., New York, NY 10017

### BIONTECH

Manufactured for BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz, Germany

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### Microbiology & Infectious Diseases

### COVID-19 RNA Based Vaccines and the Risk of Prion Disease

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#### ABSTRACT

Development of new vaccine technology has been plagued with problems in the past. The current RNA based SARS-CoV-2 vaccines were approved in the US using an emergency order without extensive long term safety testing. In this paper the Pfizer COVID-19 vaccine was evaluated for the potential to induce prion-based disease in vaccine recipients. The RNA sequence of the vaccine as well as the spike protein target interaction were analyzed for the potential to convert intracellular RNA binding proteins TAR DNA binding protein (TDP-43) and Fused in Sarcoma (FUS) into their pathologic prion conformations. The results indicate that the vaccine RNA has specific sequences that may induce TDP-43 and FUS to fold into their pathologic prion confirmations. In the current analysis a total of sixteen UG tandem repeats ( $\Psi G \Psi G$ ) were identified and additional UG ( $\Psi G$ ) rich sequences were identified. Two GGWA sequences were found. Potential G Quadruplex sequences are possibly present but a more sophisticated computer program is needed to verify these. Furthermore, the spike protein, created by the translation of the vaccine RNA, binds angiotensin converting enzyme 2 (ACE2), a zinc containing enzyme. This interaction has the potential to increase intracellular zinc. Zinc ions have been shown to cause the transformation of TDP-43 to its pathologic prion configuration. The folding of TDP-43 and FUS into their pathologic prion confirmations is known to cause ALS, front temporal lobar degeneration, Alzheimer's disease and other neurological degenerative diseases. The enclosed finding as well as additional potential risks leads the author to believe that regulatory approval of the RNA based vaccines for SARS-CoV-2 was premature and that the vaccine may cause much more harm than benefit.

#### Keywords

COVID-19, Vaccines, Diabetes, Immunity.

#### Introduction

Vaccines have been found to cause a host of chronic, late developing adverse events. Some adverse events like type 1 diabetes may not occur until 3-4 years after a vaccine is administered [1]. In the example of type 1 diabetes the frequency of cases of adverse events may surpass the frequency of cases of severe infectious disease the vaccine was designed to prevent. Given that type 1 diabetes is only one of many immune mediated diseases potentially caused by vaccines, chronic late occurring adverse events are a serious public health issue.

The advent of new vaccine technology creates new potential mechanisms of vaccine adverse events. For example, the first killed polio vaccine actually caused polio in recipients because the up scaled manufacturing process did not effectively kill the polio virus before it was injected into patients. RNA based vaccines offers special risks of inducing specific adverse events. One such potential adverse event is prion based diseases caused by activation of intrinsic proteins to form prions. A wealth of knowledge has been published on a class of RNA binding proteins shown to participating in causing a number of neurological diseases including Alzheimer's disease and ALS. TDP-43 and FUS are among the best studied of these proteins [2].

The Pfizer RNA based COVID-19 vaccine was approved by the US FDA under an emergency use authorization without long term safety data. Because of concerns about the safety of this vaccine a study was performed to determine if the vaccine could potentially induce prion based disease.

#### Methods

Pfizer's RNA based vaccine against COVID-19 was evaluated for the potential to convert TDP-43 and or FUS to their prion based disease causing states. The vaccine RNA was analyzed for the presence of sequences that can activate TDP-43 and FUS. The interaction of the transcribed spike protein with its target was analyzed to determine if this action could also activate TDP-43 and FUS.

### Results

Analysis of the Pfizer vaccine against COVID-19 identified two potential risk factors for inducing prion disease is humans. The RNA sequence in the vaccine [3] contains sequences believed to induce TDP-43 and FUS to aggregate in their prion based conformation leading to the development of common neurodegerative diseases. In particular it has been shown that RNA sequences GGUA [4], UG rich sequences [5], UG tandem repeats [6], and G Quadruplex sequences [7], have increased affinity to bind TDP-43 and or FUS and may cause TDP-43 or FUS to take their pathologic configurations in the cytoplasm. In the current analysis a total of sixteen UG tandem repeats ( $\Psi G \Psi G$ ) were identified and additional UG ( $\Psi G$ ) rich sequences were identified. Two GG $\Psi A$  sequences were found. G Quadruplex sequences are possibly present but sophisticated computer programs are needed to verify these.

The spike protein encoded by the vaccine binds angiotensin converting enzyme 2 (ACE2), an enzyme which contains zinc molecules [8]. The binding of spike protein to ACE2 has the potential to release the zinc molecule, an ion that causes TDP-43 to assume its pathologic prion transformation [9].

### Discussion

There is an old saying in medicine that "the cure may be worse than the disease." The phrase can be applied to vaccines. In the current paper the concern is raised that the RNA based COVID vaccines have the potential to cause more disease than the epidemic of COVID-19. This paper focuses on a novel potential adverse event mechanism causing prion disease which could be even more common and debilitating than the viral infection the vaccine is designed to prevent. While this paper focuses on one potential adverse event there are multiple other potential fatal adverse events as discussed below.

Over the last two decades there has been a concern among certain scientists that prions could be used as bioweapons. More recently there has been a concern that ubiquitous intracellular molecules could be activated to cause prion disease including Alzheimer's disease, ALS and other neurodegenerative diseases. This concern originates due to potential for misuse of research data on the mechanisms by which certain RNA binding proteins like TDP-43, FUS and others can be activated to form disease causing prions. The fact that this research, which could be used for bioweapons development, is funded by private organizations including the Bill and Melinda Gates Foundation, and Ellison Medical Foundation [2] without national/international oversight is also a concern. In the past, for example, there were prohibitions for publishing information pertaining to construction of nuclear bombs. Published data has shown that there are several different factors that can contribute to the conversion of certain RNA binding proteins including TDP-43, FUS and related molecules to their pathologic states. These RNA binding proteins have many functions and are found in both the nucleus and the cytoplasm. These binding proteins have amino acid regions, binding motifs that bind specific RNA sequences. Binding to certain RNA sequences when the proteins are in the cytoplasm is believed to causes the molecules to fold in certain ways leading to pathologic aggregation and prion formation in the cytoplasm [2]. The current analysis indicates Pfizer's RNA based COVID-19 vaccine contains many of these RNA sequences that have been shown to have high affinity for TDP-43 or FUS and have the potential to induce chronic degenerative neurological diseases.

Zinc binding to the RNA recognition motif of TDP-43 is another mechanism leading to formation of amyloid like aggregations [9]. The viral spike protein, coded by the vaccine RNA sequence, binds ACE2 an enzyme containing zinc molecules [8]. This interaction has the potential to increase intracellular zinc levels leading to prion disease. The initial binding could be between spike proteins on the surface of the cell transfected by the vaccine and ACE2 on the surface of an adjacent cell. The resulting complex may become internalized. Alternatively, the interaction could initially take place in the cytoplasm of a cell that makes ACE2 and has been transfected with the vaccine RNA coding for the spike protein. The interaction is quite concerning given the belief that the virus causing COVID-19, SARS-CoV-2, is a bioweapon [10,11] and it is possible that the viral spike protein may have been designed to cause prion disease.

Another related concern is that the Pfizer vaccine uses a unique RNA nucleoside 1-methyl-3'-pseudouridylyl ( $\Psi$ ). According to FDA briefing documents, this nucleoside was chosen to reduce activation of the innate immune system [12]. RNA molecules containing this nucleoside will undoubtedly have altered binding [13]. Unfortunately, the effect on TDP-43, FUS and other RNA binding proteins is not published. The use of this nucleoside in a vaccine can potentially enhance the binding affinity of RNA sequences capable of causing TDP-43 and FUS to assume toxic configurations.

There are many other potential adverse events that can be induced by the novel RNA based vaccines against COVID-19. The vaccine places a novel molecule, spike protein, in/on the surface of host cells. This spike protein is a potential receptor for another possibly novel infectious agent. If those who argue that the COVID-19 is actually a bioweapon are correct, then a second potentially more dangerous virus may be released that binds spike protein found on the host cells of vaccine recipients. Data is not publicly available to provide information on how long the vaccine RNA is translated in the vaccine recipient and how long after translation the spike protein will be present in the recipient's cells. Such studies pertaining to in vivo expression will be complex and challenging. Genetic diversity protects species from mass casualties caused by infectious agents. One individual may be killed by a virus while another may have no ill effects from the same virus. By placing the identical receptor, the spike protein, on cells of everyone in a population, the genetic diversity for at least one potential receptor disappears. Everyone in the population now becomes potentially susceptible to binding with the same infectious agent.

Autoimmunity and the opposing condition, metabolic syndrome, are well know adverse events caused by vaccines [14]. COVID-19 infections are associated with the induction of autoantibodies and autoimmune disease [15,16] making it more than plausible a vaccine could do the same. One author has found amino acid sequences coded by the spike protein to be identical to sequences in human proteins including proteins found in the CNS [17]. Autoimmunity can also be induced by epitope spreading when a foreign antigen, like the spike protein, is presented by an antigen presenting cell that also has self molecules attached to its MHC molecules.

Finally, others working in the field have published additional support that COVID-19 vaccines could potentially induce prion disease. Authors [18] found prion related sequences in the COVID-19 spike protein which were not found in related coronaviruses. Others [19] have reported a case of prion disease, Creutzfeldt-Jakob disease, initially occurring in a man with COVID-19.

Many have raised the warning that the current epidemic of COVID-19 is actually the result of an bioweapons attack released in part by individuals in the United States government [10,11]. Such a theory is not far fetched given that the 2001 anthrax attack in the US originated at Fort Detrick, a US army bioweapon facility. Because the FBI's anthrax investigation was closed against the advice of the lead FBI agent in the case, there are likely conspirators still working in the US government. In such a scenario the primary focus of stopping a bioweapons attack must be to apprehend the conspirators or the attacks will never cease. Approving a vaccine, utilizing novel RNA technology without extensive testing is extremely dangerous. The vaccine could be a bioweapon and even more dangerous than the original infection.

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### 20 Mechanisms of Injuries (MOI) How COVID-19 Injections Can Make You Sick; Even Kill You

By Dr. Sherri Tenpenny Cleveland, Ohio <u>www.DrTenpenny.com</u> C 2021

### **Definitions:**

J&J – Johnson and Johnson – uses adenovirus and transgene to create the spike protein
 AZ – AstraZeneca – uses adenovirus and transgene to create spike proteins; high risk of blood clots
 Pfizer and Moderna – use mRNA to create the spike protein

**Spike protein** – antigen on surface of the SARS-CoV2 virus that binds to the ACE2 receptors on the surface of cells to enter into organs to start replication.

**Anti-S-Antibody** – the antibody generated by your immune system B-cells after being exposed to the Spike protein; the antibody is supposed to bind to the spike protein on the surface of the virus to block entrance into the cells. However it is not known if this actually occurs.

**MOI #1** – Injections can lead to death through anaphylactic shock, a life-threatening allergic reaction. With COVID shots, the allergic reaction is suspected to be caused by previous exposure to and sensitization to polyethylene glycol [PEG].

**MOI #2** – Anti-Inflammatory macrophages, called M2, are inhibited by anti-spike-antibodies [anti-S-Ab].

**MOI #3** – All COVID shots lead to the creation of a spike protein through a process called translation. The spike protein can damage the body by **at least FOUR pathways:** 

- 1. The spike protein behaves as a hapten, a small molecule that binds to the surface of organs, leading to an autoimmune response.
- 2. The spike protein can damage organs directly by promoting cardiovascular complications, damaging blood vessels in the lungs, and breaking through the blood brain barrier (BBB), important for protecting the brain.
- 3. The spike protein can incorporate into human DNA through a process called transfection.
- 4. The spike protein evokes the release of destructive anti-spike-antibodies, [anti-S-Ab] discussed below.

**MOI #4** – Spike protein can trigger changes in blood vessel walls, leading to **pulmonary artery hypertension (PAH**), which is fatal even under the best current conventional and alternative treatments.

**MOI #5** – In men, the **spike protein** can bind to the ACE2 receptor on sperm. **Risk of infertility** is indicated but not yet proven.

**MOI #6** – Spike proteins cause inflammation and disruption of the **blood brain barrier (BBB)**, leading to **neuropathology and brain degeneration**.

**MOI #7** – Neurological degeneration: spike proteins can damage the *FUS* gene and mutate the *TDP-43 protein*, leading to **Amyotrophic Lateral Sclerosis (ALS)**.

**MOI #8** – Neurological degeneration: mutation and altered function of the TDP-43 protein can also lead to frontotemporal lobe degeneration (FTLD), a cluster of chronic, degenerative neurological diseases.

MOI #9 – Mutation of the FUS gene can also lead to cancer.

**MOI #10** – **Adenoviruses** used in both the Johnson & Johnson shot and the AstraZeneca shots pose **a risk of cancer**.

**MOI #11** – Anti-spike-antibodies **[anti-S-Ab]** can cause significant damage, specifically to the lungs. The antibodies can also cross-react with **28 different human tissue types**, establishing a mechanism for **multi-system autoimmune disorders and multiorgan failure.** 

**MOI #12** – Previous coronavirus exposure and the concept called **'original antigenic sin'** stops true protection against the SARS-CoV2 if previously ill with a coronavirus infection.

**MOI #13** – There is an **increased risk of COVID illness and COVID-related death** in persons who has been previously vaccinated with an **influenza vaccine**.

**MOI #14** – The larger (highly elevated) SARS-CoV-2 antibody response from a COVID infection or from a COVID shot, **results in prolonged and more severe illness.** 

**MOI #15** – COVID shots can lead to **enlarged lymph nodes** that may have long term ramifications.

**MOI #16** – Widespread use of COVID shots results **in non-neutralizing antibodies**, especially in people who have already had a COVID infection. This may be leading to **virulent mutant viruses**.

**MOI #17** – **Antibody Dependent Enhancement (ADE)** is a phenomenon occurs when a person is exposed to a circulating coronavirus after being vaccinated. The anti-S-Ab enhances the entry of the SARS-CoV-2 virus into the cell (usually macrophages) and accelerates its replication, causing more severe illness than they would have experienced if they had not been vaccinated.

**MOI #18** – Johnson/Johnson and AstraZeneca shots release **a transgene** that can lead to potentially deadly side effects from injecting raw genetic material that **can induce anti-DNA antibodies and can integrate into human DNA.** 

**MOI #19** – Both Johnson/Johnson and AstraZeneca shots carry a snip of double stranded DNA (dsDNA) [transgene] wrapped in an adenovirus outer "shell." 50-billion particles are injected with each injection. dsDNA-antibodies are diagnostic of a long list of autoimmune disorders.

**MOI #20:** The AstraZeneca shot has been known to be associated with potentially deadly blood clots, a condition named Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT).

### 

"Approving a vaccine, utilizing novel RNA technology without extensive testing is extremely dangerous. The vaccine could be a bioweapon and even more dangerous than the original infection."

**REF:** Classen JB. COVID-19 RNA Based Vaccines and the Risk of Prion Disease. Microbiol Infect Dis. 2021; 5(1): 1-3. <u>https://scivisionpub.com/pdfs/covid19-rna-based-vaccines-and-the-risk-of-prion-disease-1503.pdf</u>

By Dr. Sherri Tenpenny Cleveland, Ohio

# 20 Mechanisms of Injuries (MOI)

### How COVID -19 Injections Can Make You Sick...Even Kill You



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May 6, 2021

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"Approving a vaccine, utilizing novel RNA technology without extensive testing is extremely dangerous. The vaccine could be a bioweapon and even more dangerous than the original infection."

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By injecting the synthetically made SARS-CoV-2 spike protein into the entire population through these genetic-modification injections, the risk of longterm side effects and risk of developing an autoimmune illness will remain for an unknown period of time. However, with B-cell priming and irreversible genetic manipulation, the risk for developing chronic illness or sudden death could last forever.



### MOI #1 Anaphylactic shock

- Anaphylaxis is a severe, potentially life-threatening allergic reaction. It can occur within seconds or minutes of exposure to something you're allergic to, such as peanuts or bee stings.
- Injections can lead to death through anaphylactic shock, life-threatening allergic reactions. With COVID shots, the allergic reaction is suspected to be caused by previous sensitization to polyethylene glycol [PEG].
- **Polyethylene glycol (PEG)** is a water-soluble synthetic polymer consisting of repeating units of ethylene glycol. It is used to cover injected proteins to protect them from being broken down by enzymes.
- PEG is widely used in cosmetics, hygiene products, dental products, food and pharmaceuticals. There are 20 approved childhood and adults vaccines that contain polysorbate 20 or polysorbate 80.
- **PEG and polysorbate** are structurally related, and cross-reactive hypersensitivity between these compounds may occur.
- So many products now contain PEG, exposure is nearly unavoidable. Upward of 70% of the general public have anti-PEG antibodies compared with 0.2% two decades ago.
- Patients with high levels of anti-PEG IgG antibodies can experience severe allergic reactions and anaphylaxis when re-exposed to injected PEG.
- G Known allergy to PEG, or polysorbate, is a contraindication to vaccination.
  - REF: Moreno, Angelo, et al. "Anti-PEG Antibodies Inhibit the Anticoagulant Activity of PEGylated Aptamers." Cell Chemical Biology. Vol 26, Issue 5, 2019. Pages 634-644.e3. <u>https://www.sciencedirect.com/science/article/pii/S2451945619300352</u>

**UPDATE:** March 5, 2021: A change from previous versions of the guidance, known polysorbate allergy is no longer a contraindication to mRNA vaccinations; avoiding the Pfizer or the Moderna shot is merely a "recommendation." This is similar to people who have had anaphylactic reactions to eggs: for example, avoiding measles or influenza vaccines made with eggs is 'recommended' not a 'contraindication.'

Known polysorbate allergy remains a contraindication to Janssen COVID-19 vaccine. **REF:** <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</u>

# MOI #2 Anti-inflammatory macrophages, called M2, are inhibited by anti-spike -antibodies [Anti-S-Ab]

- Macrophages are a type of white blood cell that leave the blood stream and migrate into tissues when the tissues become infected. They engulf the pathogen and eliminates it.
- There are two primary types of macrophages: **type M1**, which are pro-inflammatory and are the first to arrive to "fight" the infection; and **type M2**, which are anti-inflammatory, which arrive as the "fire department" [to eliminate the cytokines] and the "clean-up crew" [to remove cellular debris as healing occurs.]
- The anti-S-antibodies [anti-S-Ab] skew the configuration toward cytokine producing macrophages (M1) by inhibiting the inflammation-resolving (M2) macrophages. This causes lung injury by promoting the uncontrolled release of proinflammatory cytokines, IL-8, IL-10, MCP1 and others.
- Animals that had been vaccinated and then contracted a SARS-CoV infection on re-exposure had an accumulation of pro-inflammatory macrophages (M1) and an **absence of woundhealing (M2) macrophages in the lungs.** 
  - REF: Li Liu, et al. "Anti–spike IgG causes severe acute lung injury by skewing macrophage responses during acute SARS-CoV infection. JCI Insight. 2019;4(4):e123158. <u>https://doi.org/10.1172/jci.insight.123158</u>





### MOI #3 The damaging effects of the spike protein

- The spike protein can bind to the surface of the vaccine recipient's cells. This spike protein becomes a potential receptor for other more aggressive or more dangerous infectious agents.
  - REF: Classen JB. COVID-19 RNA Based Vaccines and the Risk of Prion Disease. Microbiol Infect Dis. 2021; 5(1): 1-3. <u>https://carterheavyindustries.files.wordpress.com/2021/02/covid19-rnabased-vaccines-and-the-risk-of-prion-disease-1503.pdf</u>
- SARS-CoV-2 is the only coronavirus with a prion-like domain found in the receptor-binding domain of the S1 region of the spike protein. SARS-CoV-2 demonstrates a 10- to 20-fold higher affinity for ACE2 receptor, their primary binding site, than SARS-CoV and other common coronaviruses.
  - **REF:** Tetz, G.; Tetz, V. SARS-CoV-2 Prion-Like Domains in Spike Proteins Enable Higher Affinity to ACE2. Preprints 2020, 2020030422 (doi: 10.20944/preprints202003.0422.v1) [Note: The SARS-CoV-2 virus is the only coronavirus with this receptor and affinity because SARS-CoV-2 was made/manufactured in a lab. The tighter the spike protein binds to the ACE receptor, the easier it is to enter the cell and replicate.]
- The SARS-CoV-2 spike protein may promote cardiovascular complications by binding to coronary (heart) blood vessels eliciting other cardiovascular diseases such as arrhythmias, coronary artery disease, hypertension, and stroke.
  - **REF:** Suzuki, Yuichiro J, and Sergiy G Gychka. "SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines." Vaccines. vol. 9,1 36. 11 Jan. 2021. <u>https://www.mdpi.com/2076-393X/9/1/36/htm</u>

### MOI #4 The spike protein and risk of pulmonary artery hypertension (PAH)

- The SARS-CoV-2 spike protein can bind to ACE2 receptors and can promote pulmonary vascular wall thickening, that is a hallmark of pulmonary arterial hypertension (PAH).
- It is important to consider that the spike protein produced by the COVID-19 vaccines may do the same things.

### **NOTE:** PAH is uniformly fatal. Even with currently available therapies, up to 70% die within 3yrs.

 REF: Suzuki, Yuichiro J, and Sergiy G Gychka. "SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines." Vaccines. vol. 9,1 36. 11 Jan. 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7827936/



# MOI #5 The spike protein can bind to the ACE2 receptors on sperm and ovaries

- SARS-CoV-2 uses its spike protein to bind to angiotensin-converting enzyme 2 (ACE2) to enter human host cells. **Risk of infertility is possible but not yet proven.**
- ACE2 receptors are expressed on lung, intestine, and kidney tissues and also on the testis, sperm, ovaries, uterus, and vagina. The reproductive consequences of the spike protein whether from the virus or as a consequence of being injected with one of the COVID shots such as infertility and the risk of sexual transmission, are currently unknown. However, we should be alert to the possibility that there may be reproductive consequences of COVID-19 infection in males.
  - **REF:** Sheikh Zadeh Hesari F, et al. "Review of COVID-19 and male genital tract." Andrologia. 2021 Feb;53(1):e13914. <u>https://pubmed.ncbi.nlm.nih.gov/33236375</u>
  - REF: Morelli, Fabrício et al. "COVID-19 Infection in the Human Reproductive Tract of Men and Nonpregnant Women." The American journal of tropical medicine and hygiene, vol. 104,3 814– 825. 18 Jan. 2021. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7941816/</u>

### **Neurological degeneration: Penetrating the** MOI #6 **Blood Brain Barrier (BBB)**

- SARS-CoV-2 spike protein induces **loss of the BBB integrity** by triggering a proinflammatory response and upregulating enzymes (metalloproteinases - MMPs) in the barrier's cells.
- Breaking down the BBB means many particles can pass directly into brain tissue. This 0 explains the neurological conditions associated with the SARS-CoV-2 spike protein: loss of smell, loss of taste, headache, seizures, uncontrolled tremors, etc.
  - **REF:** Buzhdygana, Tetayna P, et al. "The SARS-CoV-2 spike protein alters barrier function in 2D static and 3D microfluidic in-vitro models of the human blood-brain barrier." Neurobiology of Disease, 146 (2020) 15113.

https://www.sciencedirect.com/science/article/pii/S096999612030406X?via%3Dihub

This is a short, representative list of neurological disorders associated with loss of BBB integrity

- Extrinsic:
  - Multiple Sclerosis autoimmune, infectious, traumatic initiation
  - Meningitis bacterial, viral
  - Encephalitis herpes, HIV, etc.
- Intrinsic:
  - Ischemia/hypoxia
  - Traumatic brain injury edema, hemorrhage
  - Small vessel disease hypertension, diabetes
    - REF: Rosenberg, Gary A. "Neurological diseases in relation to the blood-brain barrier." Journal of cerebral blood flow and metabolism : official journal of the International Society of Cerebral Blood Flow and Metabolism vol. 32,7 (2012): 1139-51. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3390801/





### MOI #7 Neurological degeneration: Amyotrophic Lateral Sclerosis

- At least 85 mutations in the *FUS* gene have been found to cause Amyotrophic Lateral Sclerosis (ALS), a condition characterized by progressive muscle weakness, loss of muscle mass, and inability to control movement.
- People with ALS caused by *FUS* gene mutations tend to develop the disease **at a younger age** and have a **decreased life expectancy.**
- At least 60 mutations in the TARDBP gene have been found to cause ALS. The TARDBP gene makes the *TDP-43 protein*. A change in a single amino acid in the *TDP-43 protein* can cause it to misfold and form clumps, leading to the inability to control movement.
- The amino acid sequence of the Pfizer spike protein may induce mutations of the FUS gene and the TDP-43 protein, leading to pathologic configurations and brain degeneration. Mutation, or damage, to the FUS gene and/or the TDP-43 protein has been strongly associated with ALS.
  - REF: Baloh RH. "How do the RNA-binding proteins TDP-43 and FUS relate to amyotrophic lateral sclerosis and frontotemporal degeneration, and to each other?" Current Opin Neurol. 2012 Dec;25(6):701-7.
    <a href="https://pubmed.ncbi.nlm.nih.gov/23041957/">https://pubmed.ncbi.nlm.nih.gov/23041957/</a>
  - REF: MedlinePlus, National Library of Medicine. TARDP gene <u>https://medlineplus.gov/genetics/gene/tardbp/#conditions</u>

### MOI #8 Neurological degeneration: Frontotemporal Lobe Degeneration (FTLD)

- The amino acid sequence of the Pfizer spike protein can lead to mutation and altered function of the TDP-43 protein, leading to neurodegenerative disease including a group of conditions known as frontotemporal lobe degeneration (FTLD), a cluster of chronic degenerative neurological diseases.
  - REF: Baloh RH. "How do the RNA-binding proteins TDP-43 and FUS relate to amyotrophic lateral sclerosis and frontotemporal degeneration, and to each other?" Current Opin Neurol. 2012 Dec;25(6):701-7.
    <a href="https://pubmed.ncbi.nlm.nih.gov/23041957/">https://pubmed.ncbi.nlm.nih.gov/23041957/</a>

### What is frontotemporal lobe degeneration? (FTLD)

Personality characteristics of FTLD include apathy, aspontaneity, inflexibility, disorganization, impulsivity, personal neglect, and poor judgment. FTLD is a collection of various forms of dementia. Defining features of Frontal Lobe Dementia (FLD) or Frontotemporal Lobe Degeneration (FTLD) include personality and behavioral disorders.

There are several subtypes thought to be associated with protein modification or pathological transformation of FDP-43 protein in the brain. Motor neuron degeneration often co-occurs with FTLD.

### Subtypes: (various sources):

**1. Behavioral variant Frontotemporal Dementia (bv-FTD):** Early symptoms are dominated by **impairment in social behavior** and personal character. Patients say inappropriate things, ignore other peoples' feelings and have **difficulty in dealing with simple, daily situations.** Additional symptoms include a wide range of behaviors such as blurting out words and speech alterations. Binge eating is also common among bv-FTD patients.

2. Primary Progressive Aphasia (PPA): Persons with PPA experience a gradual loss of their ability to speak, write, read, and/or understand what others are saying. This progresses to complete loss of both language and memory due to deterioration of brain tissue. Eventually, almost all patients become mute and unable to understand spoken or written language, even if their behavior seems otherwise normal.

**3. Progressive non-fluent/agrammatic aphasia:** Persons with this form of FTLD have **difficulty forming words** but can retain the meaning of words. Grammar problems are a key feature, such as mixing up the order of words in a sentence.

**4. Semantic variant Primary Progressive Aphasia (svPPA):** This disorder is characterized by the **progressive, profound loss of meaning of words**. They can speak but say things that don't make sense.

They also demonstrate behavioral abnormalities due to the degeneration of the anterior temporal lobes.

**5. Logopenic aphasia (also called progressive fluent aphasia):** People with this subtype have difficulty finding the right words when they try to speak.



### MOI #9 Risk of mutating the *FUS* gene and cancer

- The amino acid sequence of the Pfizer spike protein may induce the FUS gene to form pathologic conformations, that may lead to cancer.
- Mutations in the *FUS gene* are found in soft tissue sarcomas, which develop in bones or in soft tissues such as nerves or cartilage. FUS gene mutations have also been found in myxoid liposarcomas, which occur in fatty tissues of the body, and in cancer of the blood-forming cells in the bone marrow called acute myeloid leukemia (AML).
  - **REF:** FUS gene, MedlinePlus, National Library of Medicine. <u>https://medlineplus.gov/genetics/gene/fus/#references</u>

### MOI #10 Adenoviruses and the risk of cancer

The currently authorized Johnson and Johnson injection is made from Ad26.COV-2.S shell, a human adenovirus first isolated in 1956 from an anal specimen obtained from a 9-month old male infant (<u>https://doi.org/10.1016/j.vaccine.2020.09.018</u>)

The Oxford/AstraZeneca vaccine uses ChAdOx1, which is an adenovirus strain which normally infects **chimpanzees**.

- O More than 100 serologically distinct types of adenovirus have been identified, including 49 types that infect humans.
- Most of the **adenovirus-induced tumors**, tumor cell lines, and transformed cell lines carry one or several copies of the viral genome integrated into the chromosomes.

### "Oncogenes in adenovirus-induced tumor or transformed cells have received surprisingly little attention."

- Adenoviruses are excellent antigens. However, viral vaccines usually have not included them because adenoviruses are involved in tumorigenesis in animals and in cell culture.
  - **REF:** Baron S, editor. Medical Microbiology. 4th edition. Galveston (TX): University of Texas Medical Branch at Galveston; 1996. Chapter 67 Adenoviruses by Walter Loeffler. <u>https://www.ncbi.nlm.nih.gov/books/NBK8503/</u>
- Ad26.COV2.S used in the J&J shot has been designed to deliver a transgene encoding to create the SARS-CoV-2 the spike protein. Ad26 vector-based vaccines are manufactured using PER.C6 cell line, from retina cells of an aborted human fetus.
  - REF: Janssen BioNTech, Inc. COVID-19 Vaccine Ad26.COV2.S VAC31518 (JNJ-78436735) Briefing document. VRBPAC meeting. Feb. 26, 2021. pg. 12 <u>https://www.fda.gov/media/146219/download#page=96</u>
- Transgenics refers to the movement of genes between organisms of different species. The transferred gene is called a transgene. Transgenes can alter the phenotype [genetics] of the receiver. A transgene can be used by the cell to produce a new protein that the cell could not make before.
  - **REF:** How Genetic Engineering Can Be Used To Produce Human Insulin <u>https://diabetestalk.net/insulin/how-genetic-engineering-can-be-used-to-produce-human-insulin</u>
- The transgene can randomly insert into the genome. When a transgene incorporates into the host's DNA, it can lead to chromosome instability.
  - **REF:** Davis, Jennifer, et al. Lost in Transgenesis: A User's Guide for Genetically Manipulating the Mouse in Cardiac Research. Circulation Research. 2012; 11:761-777. <u>https://www.ahajournals.org/doi/10.1161/CIRCRESAHA.111.262717</u>



### **MOI #11** The damaging effects of the anti-S-antibody

- There was a direct, positive correlation between the level of anti-spike antibody in the blood stream and the degree of serious lung injury in the Macaque monkeys.
- The lung tissue had evidence of diffuse alveolar damage (DAD), with various degrees of exudate (pus-like fluid) and hemorrhage (bleeding).
- **C** The anti-spike antibody caused severe acute lung injury (ALI) when the animals were re-infected by suppressing the inflammation-resolving M2 macrophages.
  - REF: Li Liu, et al. "Anti–spike IgG causes severe acute lung injury by skewing macrophage responses during acute SARS-CoV infection. JCI Insight. 2019;4(4):e123158. <u>https://doi.org/10.1172/jci.insight.123158</u>
- In severe cases of COVID illness, multiple organs can be inflamed, including the lung, heart, liver, and kidney. There can also be inflammation in the blood and nervous system, leading to multi-organ failure. SARS-CoV-2 can directly invade the organ's cells through the ACE2 receptors on and within these organs.
- In addition, activation of the complement system, cytokine storm, dysregulated immune responses, coagulation dysfunction, and infiltration of inflammatory cells in SARS-CoV-2 infection can also lead to multi-organ failure in these patients.
  - REF: Mokhtari, Tahmineh et al. "COVID-19 and multiorgan failure: A narrative review on potential mechanisms." Journal of molecular histology vol. 51,6 (2020): 613-628. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7533045/</u>
- SARS-Cov-2 antibodies to the spike protein and the surface nucleoprotein crossreacted with 28 out of 55 tissue types tested. The reactions occurred in gut and barrier proteins, gastrointestinal system cells, the mitochondria, and in the tissues of the thyroid, nervous system, heart, joints, skin, muscle, and liver.
  - REF: Vojdani, Aristo, et al. "Reaction of Human Monoclonal Antibodies to SARS-CoV-2 Proteins With Tissue Antigens: Implications for Autoimmune Diseases." Front. Immunol., 19 January 2021 <u>https://doi.org/10.3389/fimmu.2020.617089</u>

### MOI #12 The concept called 'original antigenic sin' [See Diagram #4 below]

Let's use an example to explain "original antigenic sin"

- When a person is exposed to a coronavirus, the immune system responds with the release of a very specific IgG antibody formed against this FIRST coronavirus.
- When later exposed to the SARS-CoV-2 virus, B-cells "remember" the first coronavirus exposure, even if it was many years ago.
- The B-cells produce "memory antibodies," not antibodies to the SARS-CoV-2 virus. These antibodies are inadequate and are referred to as non-neutralizing, non-binding antibodies.
- They do not protect against the new "invader" but instead, enhance the infection. The person can become very ill through a phenomenon called antibody dependent enhancement (ADE). ADE elicits sustained inflammation, lymphopenia, and sometimes, cytokine storm. All of these have been associated with coronavirus severe illness and death.
  - **REF**: Firez, Walter Fierz and Walz, Brigitte Walz. "Antibody Dependent Enhancement Due to Original Antigenic Sin and the Development of SARS" Front. Immunol., 05 June 2020. https://www.frontiersin.org/articles/10.3389/fimmu.2020.01120/full
  - **REF**: Monto, Arnold S et al. "The Doctrine of Original Antigenic Sin: Separating Good from Evil." The Journal of Infectious Diseases. Vol. 215,12 (2017): 1782-1788. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5853211/#CIT0002
  - **REF**: Vatti A, et al. "Original antigenic sin: A comprehensive review." J Autoimmune. 2017 Sep;83:12-21. https://pubmed.ncbi.nlm.nih.gov/28479213/



### MOI #13 Increased risk of COVID illness and COVIDrelated death after an influenza vaccines

- C Receiving an influenza vaccination may increase the risk of illness by other respiratory viruses, a phenomenon known as **viral interference**. Viral interference has been significantly associated with coronaviruses and human metapneumoviruses.
- Examining infection caused by non-influenza viruses showed the odds of contracting coronavirus in individuals who have received an influenza vaccine were significantly higher when compared to unvaccinated individuals.
- The odds ratio (the association between an exposure and an outcome) of 1.36. In other words, the vaccinated were 36% more likely to get coronavirus illness.
  - REF: Wolf, Greg G. "Influenza vaccination and respiratory virus interference among Department of Defense personnel during the 2017–2018 influenza season." Vaccine, Volume 38, Issue 2, 2020, Pages 350-354. https://www.sciencedirect.com/science/article/pii/S0264410X19313647?via%3Dihub
- For the US and 26 European countries assessed, the results indicated that COVID-19 deaths per million inhabitants [DPMI] and the COVID-19 case fatality ratio [CFR] were positively and statistically significantly associated with influenza vaccination rate, especially in people ≥65 years old. [i.e. COVID deaths were positively associated with flu shots].
  - **REF**: Wehenkel C. 2020. Positive association between COVID-19 deaths and influenza vaccination rates in elderly people worldwide. PeerJ 8:e10112 DOI 10.7717/peerj.10112. https://peerj.com/articles/10112/



# MOI #14 High (strong) antibody responses to both COVID illness and to the shots results in prolonged illness and worse outcomes

- When an mRNA shot (Pfizer or Moderna) is given to a person who recovered from a COVID infection, small-scale studies have shown that a single mRNA injection rapidly boosts antibody titers (concentrations) to very high levels.
  - **REF**: Moore, John. "Approaches for Optimal Use of Different COVID-19 Vaccines: Issues of Viral Variants and Vaccine Efficacy." JAMA. Published online March 4, 2021. <u>https://jamanetwork.com/journals/jama/fullarticle/2777390</u>
- A robust antibody response is associated with delayed viral clearance and increased severity of infection. Patients with a strong antibody response had only 9% of virus clearance at seven days, whereas 57% of people who had a weak antibody cleared the virus in seven days.
- Further, if IgM antibody was released at the same time the person was developing a high IgG antibody response, the person had a much more severe infection.
  - **REF**: Fierz, Walter and Walz, Brigitte Walz. "Antibody Dependent Enhancement Due to Original Antigenic Sin and the Development of SARS." Front. Immunol., 05 June 2020. https://www.frontiersin.org/articles/10.3389/fimmu.2020.01120/full



## MOI #15 COVID shots lead to enlarged lymph nodes that may have long term ramifications

Efforts are being made to enhance the efficacy of COVID shots by using adjuvants, particularly adjuvants targeting the Toll-like receptors (TLRs).

0

mRNA can be used to create nearly any protein. Moderna's patent describes an mRNA for the production of an experimental adjuvant: **flagellin**. Moderna's patent lists dozens of possible mRNAs targeted to be in future shots, referring to them as "some embodiments"

The administration of flagellin or flagellin-based vaccines has been shown to rapidly achieve a **higher concentration in draining lymph nodes**.

### Is mRNA coded for flagellin already in the current shots?

• **Mammogram warning**: Lymphadenopathy was detected unilaterally in the arm and neck within 2-4 days of vaccination and lasted on average 10 days on exam. The duration of subclinical adenopathy on mammography is likely to be greater and is likely to last longer.

### **RECOMMENDATION:** Schedule screening exams prior to the first dose of a COVID-19 vaccination or 4-6 weeks following the second dose of a COVID-19 vaccination.

• **REF**: Society for Breast Imaging: Recommendations for the Management of Axillary Adenopathy in Patients with Recent COVID-19 Vaccination. https://www.sbionline.org/Portals/0/Position Statements/2021/SBI-recommendations-for-managingaxillary-adenopathy-post-COVID-vaccination.pdf



### MOI #16 Widespread use of COVID shots results in nonneutralizing antibodies and can lead to virulent mutant viral serotypes (strains)

- The combination of high viral replication rate in individuals who also produce suboptimal, non-neutralizing antibodies creates the exact environment in which **resistant viruses are likely to emerge and spread.** 
  - **REF:** Moore, John. "Approaches for Optimal Use of Different COVID-19 Vaccines: Issues of Viral Variants and Vaccine Efficacy." JAMA. Published online March 4, 2021. https://jamanetwork.com/journals/jama/fullarticle/2777390
- The antibody response to mRNA shots is higher than titers seen in convalescent (recovering) individuals. This results in a high ratio of non-neutralizing antibodies.
  - REF: Amana, Fatima et al. "The plasmablast response to SARS-CoV-2 mRNA vaccination is dominated by non-neutralizing antibodies that target both the NTD and the RBD." medRxiv 2021.03.07.21253098. https://www.medrxiv.org/content/10.1101/2021.03.07.21253098v1.full

### MOI #17 Antibody Dependent Enhancement (ADE) upon re-exposure to circulating coronavirus causes extensive illness

### Because SARS-CoV and SARS-CoV-2 viruses have approximately 78-85% genetic overlap, it is presumed a reaction would be similar in both.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7827936/

- There is a growing concern for individuals who have received a COVID shot and the pathology (illness) that will develop when these individuals are re-exposed to common coronaviruses or the SARS-CoV-2 virus.
  - All test animals had autoimmune injury to their lungs after a re-exposure.
  - Exposure to SARS-CoV is associated with prominent inflammatory infiltrates (pneumonia) characterized by a **predominant eosinophilic (allergic) component.**

Vaccinated macaques monkeys: Lung tissue revealed acute diffuse alveolar (ADA) injury with various degrees of severity at 7 and 35-days post-infection. Wound healing was blocked by anti-S-IgG antibodies, resulting in prolonged macrophage activity and promotion of severe lung injury.

Unvaccinated macaques: Lung tissue revealed only minor to moderate inflammation.
 Alveolar monocytes/macrophages assume a wound-healing function as early as two days after onset of infection in macaques who were unvaccinated.

- **REF:** Li Liu, et al. "Anti–spike IgG causes severe acute lung injury by skewing macrophage responses during acute SARS-CoV infection. JCI Insight. 2019;4(4):e123158. https://doi.org/10.1172/jci.insight.123158
- **REF:** Jason A.Tetro. "Is COVID-19 receiving ADE from other coronaviruses?" Microbes and Infection Vol 22, Issue 2, March 2020, Pages 72-73. https://www.sciencedirect.com/science/article/abs/pii/S1286457920300344?via%3Dihub

### MOI #18 Injecting raw genetic material can induce anti-DNA antibodies. DNA can integrate into the human DNA.

- **Both** the Johnson/Johnson shot and the AstraZeneca shot are designed to deliver doublestranded DNA (ds-DNA) fragments to the cytoplasm of the cells called a transgene.
- **A transgene** is a segment of DNA used to introduce genes from one organism to another organism. In this instance, the DNA is inserted into the recipient's DNA.
- It is presumed that the DNA is translated into mRNA, leading to the production of the spike protein and anti-spike-antibody. The use of a transgene is considered to be a genetic engineering technique.
  - **REF:** Dr. Mae Wan-Ho. "Transgenic Lines Unstable hence Illegal and Ineligible for Protection." <u>https://www.i-sis.org.uk/transgenicLinesUnstable2.php</u>

### **O** Induction of anti-DNA antibodies

- Stray DNA, similar to the spike proteins, can function as a hapten by binding to the surface of organs.
- Haptens alone do not stimulate an immune response, but **when bound to a protein**, they can lead to autoimmune reactions.

### Integration of DNA into host genome

- The segment of DNA can be integrated into the human genome, which may have devastating consequences by inducing mutations in essential structural genes or in causing mutations that can lead to cancer.
  - **REF:** Bona, Constantin A, and Bot, Adrian. "Genetic Immunization." Kluwer Academic /Plenum Publishers. 2000. Pg. 9. [TEXTBOOK]

# MOI #19 Antibodies to dsDNA can lead to a long list of autoimmune disorders

- **onti-dsDNA antibody** is highly specific for **Systemic Lupus Erythematosus (SLE)**.
- anti-dsDNA antibodies were also detected in the following conditions: other autoimmune diseases, other rheumatological disorders, malignancies, infections, autoimmune hepatitis and sarcoidosis.
  - **REF:** Attar SM, Koshak EA. Medical conditions associated with a positive anti-doublestranded deoxyribonucleic acid. Saudi Med J. 2010 Jul;31(7):781-7. https://www.academia.edu/23304303/Medical\_conditions\_associated\_with\_a\_positive\_an ti\_double\_stranded\_deoxyribonucleic\_acid

### MOI #20 AstraZeneca: Potentially deadly blood clots called Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT)

- VIPIT is a newly reported condition found after the injection of the AstraZeneca COVID19 shot. The shot may be associated with blood clots and thrombocytopenia (low levels of blood platelets).
- Clots have formed in extremities and in veins draining blood from the brain. Called a cerebral venous sinus thrombosis (CVST), when a blood clot forms in the brain's venous sinuses, it prevents blood from draining out of the brain. As a result, blood cells may break and leak blood into the brain tissues, forming a hemorrhage.
- Based on available information, the case fatality of VIPIT is approximately 40%. The exact mechanism by which the AstraZeneca shot triggers VIPIT is still under investigation.
- KEY: Any patient with unusual symptoms following the injection (4 to 20 days) should be assessed by a health care provider. Symptoms associated with VIPIT include: persistent and severe headache; focal neurological symptoms (including blurred vision); shortness of breath; abdominal or chest pain; swelling and redness in a limb; or pale color and coldness in a limb.
  - **REF:** COVID-19 Vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low blood platelets https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots
  - **REF:** Pai M, et al. "Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) following AstraZeneca COVID-19 vaccination." Version 1.0. Ontario COVID-19 Science Advisory Table. 2021 Mar 26. https://doi.org/10.47326/ocsat.2021.02.17.1.0

### **Outcomes of Animal Study**

"An inactivated vaccine preparation that does not induce this result in mice, ferrets and nonhuman primates has not been reported." [translation: vaccine induces damage to lungs after re-exposure in all animals tested – mice, ferrets, monkeys]. When challenged, vaccinated mice developed Th2-type immunopathology suggesting hypersensitivity to SARS-CoV components. **Caution in proceeding to application of a SARS-CoV vaccine in humans is indicated.**"

 REF: Tseng C-T, et al. "Immunization with SARS Coronavirus Vaccines Leads to Pulmonary Immunopathology on Challenge with the SARS Virus." PLoS ONE 7(4):e35421. 2012. doi:10.1371/journal.pone.0035421 <u>https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0035421</u>













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