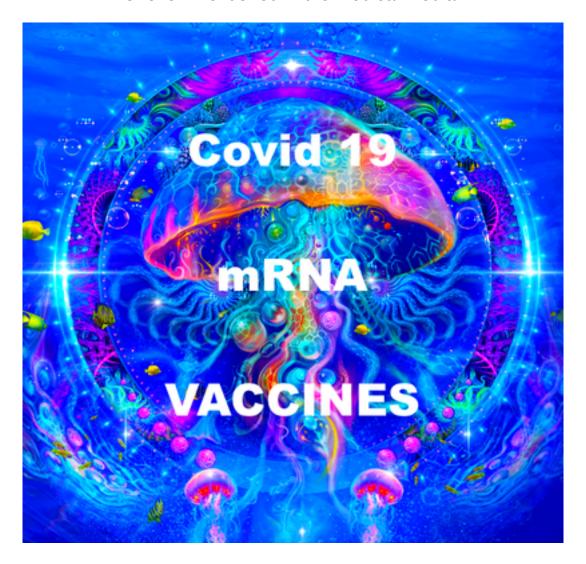
With the recent licensing and roll out
of COVID-19 vaccines, there are several serious safety concerns
that have not been addressed
or even mentioned in the medical media.



In short, it is beyond reckless and totally unnecessary to administer these experimental vaccines to millions of people when there is only limited short term safety data.

Absolutely no long-term safety studies have been done to ensure that any of these vaccines do not cause cancer, seizures, heart disease, allergies, and autoimmune diseases,

as seen with other vaccines. - https://en.wikipedia.org/wiki/RNA

#### Professor Dolores Cahill

# Why People Will Start DYING A Few Months After

# The First mRNA Vaccination

Professor Dolores Cahill: Why People Will Start DYING A Few

Months After The First mRNA Vaccination

DR. SHERRI TENPENNY

# EXPLAINS HOW THE DEPOPULATION COVID VACCINES WILL START WORKING IN 3-6 MONTHS

Doctor Explains Vaccines will Trigger De-population in 3-6 Months www.bitchute.com- m



Dr. James Odell, OMD, ND, L.Ac.

# COVID-19 mRNA Vaccines

https://www.biologicalmedicineinstitute.com/post/covid-19mrna-vaccines



With the recent licensing and roll out of COVID-19 vaccines in the U.K., Canada, the U.S. (Pfizer/ BioNTech and Moderna), and Russia (Sputnik)

# there are several serious safety concerns

that have not been addressed or even mentioned in the medical media.



In short, it is beyond reckless and totally unnecessary to administer these experimental vaccines to millions of people when there is only limited short term safety data.

Absolutely no long-term safety studies have been done to ensure that any of these vaccines do not cause cancer, seizures, heart disease, allergies, and autoimmune diseases, as seen with other vaccines and observed in earlier coronavirus vaccine animal studies.

Because animal studies were bypassed for these vaccines due to 'fast-tracking', millions of humans are now the primary test animal. Additionally, these vaccines were developed using a completely new mRNA technology that has never been licensed for human use. In essence, we have absolutely no knowledge of what to expect from these new mRNA vaccines.

Since viruses mutate frequently, the chance of any vaccine working for more than a year is unlikely. That is why the influenza (flu) vaccine changes every year. This editorial comprehensively discloses current COVID-19 vaccine development, administration, and safety concerns in detail.

Ribonucleic acid (RNA) is a nucleic acid present in all living cells. Its principal role is to act as a messenger carrying instructions from DNA for controlling the synthesis of proteins. Although in some viruses' RNA rather than DNA carries the genetic information. In each cell of a living organism, DNA is the molecule that contains the genetic information of the organism. It is composed of a series of four building blocks, whose sequence gives the instructions to fabricate proteins.

This process requires a transient intermediary called messenger RNA that carries the genetic information to the cell machinery responsible for protein synthesis. RNA is the only molecule known to recapitulate all biochemical functions of life: definition, control, and transmission of genetic information, creation of defined three-dimensional structures, enzymatic activities, and storage of energy.

RNA became the focus of intense research in molecular medicine at the beginning of the millennium. Messenger viral RNA (mRNA) is now developed as a vaccine and this technology poses many questions and serious health concerns that have been left unanswered by the vaccine manufacturers.

Unlike previous vaccines an mRNA vaccine is a new type of vaccine that inserts fragments of viral mRNA into human cells,

which are reprogrammed to produce pathogen antigens, which then if all goes well, stimulate an adaptive immune response against the targeted pathogen.

That seems straightforward, but what else is in the vaccines, and is this new technology truly proven safe and effective?

# **History of Coronavirus Vaccine Animal Studies and**

# **Antibody Dependent Enhancement (ADE)**

Researchers have been trying to develop a coronavirus vaccine since the Severe Acute Respiratory Syndrome (SARS-1) outbreak in 2002. Thus, over a span of 18 years there have been numerous coronavirus vaccine animal studies conducted, which unfortunately demonstrated significant and serious side-effects.

Either the animals were not completely protected, became severely ill with accelerated autoimmune conditions, or died.1, 2, 3, 4, 5, 6, 7

Animal side effects and deaths were primarily attributed to what is called Antibody-Dependent Enhancement (ADE). In the 1960s, immunologists discovered ADE and since then have extensively researched and identified its mechanism. Virus ADE is a biochemical mechanism in which virus-specific antibodies (usually from a vaccine) promote the entry and/or the replication of another virus into white cells such as monocytes/macrophages and granulocytic cells.

This then modulates an overly strong immune response (abnormally enhances it) and induces chronic inflammation, lymphopenia, and/or a

'cytokine storm', one or more of which have been reported to cause severe illness and even death. Essentially, ADE is a disease dissemination cycle causing individuals with secondary infection to be more immunologically upregulated than during their first infection (or prior vaccination) by a different strain. ADE of disease is always a concern for the development of vaccines and antibody therapies because the mechanisms that underlie antibody protection against any virus has a theoretical potential to amplify the infection or trigger harmful immunopathology.8, 9, 10 ADE of the viral entry has been observed and its mechanism described for many viruses including coronaviruses.11, 12, 13 Basically, it was shown that antibodies target one serotype of viruses but only sub neutralize another, leading to ADE of the latter exposed viruses.

Thus, ADA of viral entry has been a major concern and stumbling block for vaccine development and antibody-based drug therapy. For example, it has been shown that when patients are infected by one serotype of dengue virus (i.e., primary infection), they produce neutralizing antibodies targeting the same serotype of the virus.

However, if they are later infected by another serotype of dengue virus (i.e., secondary infection), the preexisting antibodies cannot fully neutralize the virus. Instead, the antibodies first bind to the virus and then bind to the IgG Fc receptors on immune cells and mediate viral entry into these cells.14 A similar mechanism has been observed for HIV, Ebola, and influenza viruses. Thus, sub neutralizing antibodies (or non-neutralizing antibodies in some cases) are responsible for ADE of these viruses.15, 16, 17, 18, 19, 20

Generally, the conclusion of some of those studies was that great caution needs to be exercised when moving forward to human trials primarily because of the potential of accelerated autoimmunity reaction.

Because ADE has been demonstrated in animals21, coronavirus vaccine research never progressed to human trials, at least not till the recent SARS coronavirus-2 fast-track campaign.

### More technical Understanding of SARS-CoV-2 ADE

#### **Mechanisms**

As a forementioned, a potential barrier to the development of safe and efficacious COVID-19 vaccines is the risk that insufficient titers of neutralizing antibodies might trigger ADE of disease. Previous research in SARS-CoV infection demonstrated ADE is mediated by the engagement of Fc receptors (FcRs) expressed on different immune cells, including monocytes, macrophages and B cells.22, 23, 24 A Fc receptor is a protein found on the surface of certain cells – including, among others, B lymphocytes, follicular dendritic cells, natural killer cells, macrophages, neutrophils, eosinophils, basophils, human platelets, and mast cells – that contribute to the protective functions of the immune system.

Akiko Iwasaki and colleagues describe this coronavirus ADE mechanism in more detail in their 2020 research published in *Nature Reviews Immunology*.25 They confirm that pre-existing SARS-CoV-specific antibodies may thus promote viral entry into FcR-expressing cells. This

process is independent of ACE2 expression and endosomal pH and proteases, suggesting distinct cellular pathways of ACE2-mediated and FcR-mediated viral entry.

In short, previous experience with veterinary coronavirus vaccines and animal models of SARS-CoV and MERS-CoV infection has raised safety concerns about the potential for ADE and/or vaccine-associated enhanced respiratory disease. These events were associated either with macrophage-tropic coronaviruses susceptible to antibody-dependent enhancement of replication or with vaccine antigens that induced antibodies with poor neutralizing activity and Th2-biased responses.

After two decades of failed animal trials, the question is posed as to why fast-tracking coronavirus vaccine will now result in a different outcome? Given that many of these fast-track trials have bypassed animal studies, are only performed on healthy volunteers and children (not the elderly or those with pre-morbidities), and that trials are conducted without an inert double-blind placebo-controlled environment, and are not given sufficient time to observe effects on the human trials, there is a serious safety concern. Many, many virologists, and epidemiologists feel this fast-track policy is a recipe for mass disaster. Microbiologist Dr. Sucharit Bhakdi and Dr. Karina Reiss in their new book *Corona, False Alarm?* give clarity to many of the issues surrounding the pandemic, especially the current coronavirus vaccines.

#### Traditional vs. mRNA Vaccines

Historically, the manufacturing process for creating vaccines involves many trade secrets and numerous other ingredients as adjuvants and

preservatives.27, 28 'Traditional or classical vaccines' may contain attenuated or inactivated viruses and bacteria or proteins, **as well as adjuvants**, **such as aluminum**, **to stimulate an immune response that produces artificial immunity**, **as well as a host of other ingredients called "excipients"**. For example, older viral vaccines for smallpox and measles vaccine contain live attenuated viruses; injectable influenza vaccines contain inactivated viruses; the recombinant hepatitis B virus vaccine is a protein subunit vaccine, while the newer human papillomavirus (HPV) virus vaccine contains virus-like particles.

To date, there are several different types of potential vaccines for COVID-19 in development, including:

Inactivated or weakened virus vaccines, which use a form of the virus that has been inactivated or weakened, but still generates an artificial immune response.

Protein-based vaccines, which use fragments of proteins or protein shells that mimic the COVID-19 virus to generate an artificial immune response.

*Viral vector vaccines*, which use a virus that has been genetically engineered to generate an artificial immune response.

RNA and DNA vaccines, that uses genetically engineered RNA or DNA to generate a protein that itself prompts an artificial immune response.

For the past two decades, researchers have been experimenting with new technology platforms, notably ones that introduce foreign DNA and RNA into cells of the body, to develop experimental vaccines for SARS, MERS, HIV, and other diseases but, historically none have been proven effective and safe for humans.

Thus, for a traditional vaccine, the antigen is introduced in the body to produce an immune response. However, in the case of DNA- or RNA-based vaccines, no antigen is introduced, only the RNA or DNA containing the genetic information to produce the antigen. That is, for this specific class of vaccines, the introduction of DNA and RNA provides the instructions to the body to produce the antigen itself.29

mRNA vaccines differ greatly in their design and biochemical mechanisms from traditional vaccines. Traditional vaccines stimulate an antibody response by injecting a human with antigens (proteins or peptides), or an attenuated virus, or a recombinant antigen-encoding viral vector. These ingredients are prepared and grown outside of the human body, which takes time, and even when they are injected into the bloodstream, they do not enter the human cell.30

In contrast, mRNA vaccines insert a synthetically created *fragment or snip* of the virus RNA sequence directly into the human cells (known as transfection). This snip of viral RNA material then activates an enzyme called reverse transcriptase which replicates that RNA snip repeatedly. **This then reprograms the cells to produce their own viral antigens,** which, if all goes as planned, stimulates an adaptive immune response,

resulting in the production of new antibodies that bind to the antigen and activate T-cells.31, 32, 33

Simply speaking, the new mRNA vaccines inject (transfects) molecules of synthetic genetic material from non-human sources (viral sequences) into our cells. Once in the cells, the genetic material interacts with our transfer RNA (tRNA) to make a foreign protein that supposedly teaches the body to destroy the virus being coded for. These created proteins are not regulated by our own DNA and are thus completely foreign to our cells. What they are fully capable of doing is completely unknown.

Till now, messenger-RNA vaccines have never been licensed for public use. In the last two decades, there has been deep-pocket funding for the development of mRNA vaccines against infectious diseases, particularly with the currently declared pandemic and vaccine fast track campaign.

Historically, their application has until recently been restricted by the instability and inefficient *in vivo* delivery of mRNA. New technological advancements in RNA biology, chemistry, stability, and delivery systems have now accelerated the development of fully synthetic mRNA vaccines. The consensus is that mRNA vaccines are faster and cheaper to produce than traditional vaccines and for vaccine manufacturers, more cost-effectiveness translates to greater profits. **Certainly, there are unique and unknown risks to messenger RNA vaccines,** including local and systemic (ADE) inflammatory responses that could lead to autoimmune conditions.

#### mRNA Vaccines Mechanisms

mRNA vaccines have strands of genetic material called mRNA inside a special coating. That coating protects the mRNA from enzymes in the body that would otherwise break it down. It also helps the mRNA enter the muscle cells near the vaccination site. mRNA vaccines use a different approach that takes advantage of the process that cells use to make proteins: cells use DNA as the template to make messenger RNA (mRNA) molecules, which are then translated to build proteins. An RNA vaccine consists of an mRNA strand that codes for a disease-specific antigen. Once the mRNA is in the cell, human biology takes over. Ribosomes read the code and build the protein, and the cells express the protein in the body. Thus, cells use the genetic information to produce the disease-specific antigen. This antigen is then displayed on the cell surface, where it is recognized by the immune system.34

mRNA vaccines have been studied before for influenza, Zika, rabies, and cytomegalovirus. The concept for the development of an mRNA vaccine is rather straightforward. Once the antigen of choice from the pathogen target is identified, the gene is sequenced, synthesized, and cloned into the DNA template plasmid. mRNA is then transcribed *in vitro*, and the vaccine is delivered to the subject. The mRNA vaccine utilizes the host cell machinery for *in vivo* translation of mRNA into the corresponding antigen, thereby mimicking a viral infection to elicit potent humoral and cellular immune responses. The final cellular location of the antigen is determined by the signal peptide and transmembrane domain. This can be intrinsic to the natural protein sequence or engineered to direct the protein to the desired cellular compartment.35, 36

Once the viral mRNA is injected into the body, it faces immune responses that are programmed to destroy it. Our cells have evolved elaborate defense mechanisms intended to destroy foreign, unprotected, or "naked" RNA. However, the susceptibility of mRNA to degradation can be reduced by modifying the RNA during synthesis. One modification is to add in 'nucleoside analogs' that resemble the normal nucleosides found within RNA (A, U, C and G,) but have minor structural changes that make the RNA more resistant to enzyme degradation by the body's ribonucleases. (Nucleosides are the structural subunit of nucleic acids such as DNA and RNA.)

Additional structural modifications and the inclusion of regulatory sequences can also improve the stability of mRNA.37 For example, the vaccine viral mRNA is delivered in the form of a complex with lipid nanoparticles, to stabilize the mRNA, making it easier to penetrate the cell, and increases the amount of antigen produced per cell.38 Lipid nanoparticle formulations also elicit a stronger immune response compared to naked mRNA.39 This is where it gets tricky and potentially dangerous because some of the lipid nanoparticles developed for these mRNA vaccines can be strongly immuno logically reactive and elicit an unwanted autoimmune reaction. PEGylated Lipid Nanoparticles

Thus, mRNA is threatened by rapid degradation by ubiquitous extracellular ribonucleases before being taken up by cells.40 The mRNA molecule is also vulnerable to destruction from temperature changes as well as our immune system. Thus, the efficacy of mRNA vaccines requires 'complexing agents' which protect RNA from degradation.

Complexation may also enhance uptake by cells and/or improve delivery to the translation machinery in the cytoplasm. To this end, mRNA is often complexed with either lipids or polymers. These mRNA vaccines are coated with PEGylated lipid nanoparticles (polyethylene glycol). This coating hides the mRNA from our immune system which ordinarily would attack and destroy kill any foreign material injected into the body. PEGylated lipid nanoparticles have been used in several different drugs for years. Unfortunately, PEGylated lipid nanoparticles have been shown to imbalance certain immune responses and can induce allergies and even autoimmune diseases.41, 42, 43, 44, 45, 46

A 2016 study in Analytical Chemistry reported detectable and sometimes high levels of anti-PEG antibodies (including first line-of-defense IgM antibodies and later stage IgG antibodies) in approximately 72% of contemporary human samples and about 56% of historical specimens from the 1970s through the 1990s. Of the 72% with PEG IgG antibodies, 8% had anti-PEG IgG antibodies > 500ng/ml., which is considered extremely elevated.47

Extrapolated to the U.S. population of 330 million who may receive this vaccine, 16.6 million may have anti-PEG antibody levels associated with adverse effects. The researchers confessed that the results were entirely unexpected.

#### The authors concluded that:

"...sensitive detection and precise quantitation of anti-PEG Ab levels in a clinical setting will be essential to ensuring the safe use of PEGylated drugs in all target patient populations going forward."

Multiple previous studies regarding the prevalence of anti-PEG antibodies in the population have stated that pre-screening should be done prior to any administration of a PEG-containing medication. Screening is likely to be even more important in the case of a vaccine intended for parenteral administration to as many people as possible that contains a substance to which a majority of the population unknowingly has anti-PEG antibodies.

#### **Production of mRNA vaccines**

To further understand PEGylated lipid nanoparticles and their role in vaccine delivery, it is helpful to understand a little more about how an mRNA vaccine is manufactured. A major manufacturing advantage of mRNA vaccines is that RNA can be produced in the laboratory from a DNA template using readily available materials, **again less expensively and faster than conventional vaccine production,** which utilize a variety of cell types such as chicken eggs or other mammalian cells such a fetal material.48 **This all comes down to economics. It is faster and cheaper to make.** 

Traditional vaccines normally contain a strong adjuvant (often aluminum) supplying an enhanced signal for the initiation of the adaptive immune response. However, it is thought that mRNA vaccines sort of have their own adjuvant effect by themselves, partly by virtue of being foreign nucleic acids. It has not been disclosed if any of these candidates (from any company) have an adjuvant added to them. (More information on adjuvants later in this article.)

Moreover, according to Arcturus, the company manufacturing the Pfizer/BioNTech lipid delivery system, this involves a multi-component delivery system called LUNAR® (Lipid-enabled and Unlocked Nucleomonomer Agent modified RNA). "This system has access to over 150 proprietary lipids that have been utilized for mRNA-based COVID-19 vaccines." 49 Basically, all we know is this involves proprietary PEGylated lipid nanoparticles.

#### **Current mRNA Vaccines and Potential Side-Effects**

According to the WHO and the Milken Institute, as of August 2020, there were 202 companies and universities worldwide working on a coronavirus vaccine. The vaccine types vary from traditionally established vaccines (*e.g.*, inactivated, and live attenuated) to vaccines that have only recently gained clinical approval (*e.g.*, subunit) to those that have never been licensed for human use, till now (*e.g.*, mRNA, DNA, non replicating viral vector, replicating viral vector). A striking feature of the vaccine development landscape for SARS coronavirus-2 is the range of technology platforms being evaluated, including nucleic acid (DNA and RNA), virus-like particle, peptide, viral vector (replicating and non-replicating), recombinant protein, live attenuated virus and inactivated virus approaches. Since November 9th, Moderna, the pharma giant Pfizer and its German collaborator BioNTech, and a Russian Institute have all offered "preliminary evidence that their mRNA spike-based vaccines can achieve greater than 90% protective efficacy."

The vaccine pharmaceutical industry contends that an mRNAbased vaccine is "safer for the patient" than classical vaccines. But is that verified true? The manufacturer's rationale is that mRNA is a non-infectious, non-integrating platform, there is no potential risk of infection or insertional mutagenesis. Since mRNA vaccines have never been licensed and have not undergone long-term testing, we cannot know this for certain. Additionally, there is also concern that these vaccine mRNA may have long-standing dire consequences on the body's immunity, fertility, and DNA integrity.

According to researchers at the University of Pennsylvania and Duke University50, mRNA vaccines have these potential safety issues:

Local and systemic inflammation.

The biodistribution and persistence of expressed immunogen.

Stimulation of auto-reactive antibodies.

Induction of a potent type 1 interferon response, which has been associated with inflammation and potential autoimmunity. Thus, identification of individuals at an increased risk of autoimmune reactions before mRNA vaccination should be undertaken.

Presence of extracellular RNA, which may contribute to edema and pathogenic thrombus formation (blood clots). Extracellular naked RNA has been shown to increase the permeability of tightly packed endothelial cells and may thus contribute to edema.51 Another study showed that extracellular RNA promoted blood coagulation and pathological thrombus formation.52

Potential toxic effects of any non-native nucleotides and delivery

system components (particularly those that have not been disclosed by manufacturers).

There is also concern about potential mRNA modifications to the genetics of the body. Once injected into the body mRNA vaccines take the RNA from the virus into the cell where it may create unwanted detrimental genetic modifications. Over the last five years, there has been an enormous increase in the amount of research into RNA modifications; this field is called epitranscriptomics. The role of DNA modification in gene regulation is well established, but much less is known about how mRNA modification influences the way genes are expressed. In fact, numerous studies have shown viral mRNAs to be implicated as a driver in some forms of cancer and autoimmune diseases.53, 54, 55, 56

Thus, long-term safety evaluation is essential and should precede the licensing of different mRNA modalities and delivery systems. Normally, vaccine development is a lengthy and complicated process, often lasting 10-15 years and involving a combination of public and private involvement. Unfortunately, the rapid worldwide competition between pharmaceutical companies to develop a COVID-19 vaccine has bypassed multiple safety controls, rendering the result both dubious and potentially dangerous for the public. Financial interests have taken precedence over the health and safety of the public. Hasty development of vaccines is always risky, and only thorough research employing all the safety precautions will lead to a safe and effective vaccine.

The current licensed COVID-19 vaccine is not being offered to pregnant women. This is because researchers do not know enough about how COVID-19 vaccination can affect children, pregnant women, or their babies. There is also no data on the safety of COVID-19 vaccines for breastfeeding women. The Pfizer/BioNTech vaccine is not available to children under age 16.

# Moderna and Pfizer Vaccine Ingredients and Dosage

As unbelievable as it sounds, neither Pfizer/BioNTech nor Moderna have 'completely' disclosed everything in their vaccines.

Apparently, to be licensed by the FDA they do not have to disclose to the public the entire composition of their vaccine. This is what we do know. Both Moderna and Pfizer/ BioNTech vaccines are mRNA vaccines and they are different in composition, delivery, and storage. They have different nucleoside analogs, and each has unique ways to essentially attenuate the capacity of messenger RNA to induce innate immunity. They each have a different complex liquid delivery system, and this is one reason why one is much more amenable to shipping and storing at minus 20° whereas the other requires shipping and storing at minus 70°.

Moderna's vaccine uses 100 micrograms of RNA per dose, while Pfizer-BioNTech's uses only 30 micrograms. In both the Moderna and Pfizer-BioNTech vaccines the mRNA is encapsulated in lipid nanoparticles (LPN). These microscopic droplets of oily liquid — about 0.1 micron in diameter — enclose and protect the mRNA as they are manufactured, transported, and injected into people. As previously mentioned, the composition of the lipid nanoparticles is different in the two vaccines.

Pfizer/BioNTech obtains their nanoparticles from Acuitas, a specialist Canadian company, while Moderna has developed its own lipid technology.

Listed ingredients of the Pfizer/BioNTech COVID-19 vaccine include:

30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2

lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis (hexane-6,1-diyl) bis (2-hexyldecanoic)

- .05 mg 2[polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- .09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol)
- .01 potassium chloride
- .01 mg monobasic potassium phosphate
- .36 mg sodium chloride
- .07 mg dibasic sodium phosphate dehydrate
- 6 mg sucrose

the diluent (.09 percent Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose

So far as revealed in the public domain Moderna's vaccine (mRNA-1273) specifically contains lipid nanoparticle dispersion containing an mRNA that encodes for the prefusion stabilized spike protein 2019-nCoV. mRNA-1273 consists of an mRNA drug substance

that is manufactured into LNPs composed of the proprietary ionizable lipid, SM-102, and 3 commercially available lipids, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine is a phosphatidylcholine with alkyl chain comprising 18 carbons), and PEG2000 DMG (1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000). Adjuvants and other biotechnology if added have not been publicly disclosed. This vaccine requires two injections given 28 days apart.

For more information on clinical trials of all corona vaccines in development visit the Regulatory Affairs Professionals Society (RAPS). 58

# mRNA Vaccine Viral Shedding and Viral Vaccine Interference

Vaccine shedding is a term used for the release of virus following administration of a live-virus vaccine. This has been particularly observed in the administration of live polio vaccines. Neither of the vaccines in distribution or in development use the live virus that causes COVID-19. Thus, current consensus among vaccine developers is that vaccine viral shedding is not expected with mRNA vaccines. However, bear in mind mRNA viral vaccines is a new platform, and this issue is in unknown territory.

Viral interference describes the situation whereby infection or vaccine inoculation with one virus limits infection and replication of a second virus. For example, epidemiological studies show that following infection with influenza virus, there is a short period during which a host

experiences a lower susceptibility to infection with other similar viruses. This viral interference appears to be independent of any antigenic similarities between the viruses. It certainly is possible that the mRNA vaccine may elicit vaccine viral interference and causes people to be more susceptible to other viruses, such as influenza.

# SARS-CoV-2 Spike Protein Shares Sequence with a Human Protein Syncytin-1

Syncytin-1 is a protein that functions for placental development and therefore is essential for fertility. Fifteen years ago, it was proposed that a synthetic Syncytin-1 vaccine could be developed as a contraceptive that would work to produce antibodies against human Syncytin-1.59

It is proposed by some doctors that the Pfizer COVID vaccine may elicit an antibody response against Syncythin-1 and cause infertility because of a similar or shared amino acid sequence in the spike protein of SARS-CoV-2 and the Syncythin-1 placental protein. Pharmaceutically sponsored fact-checkers, and Pfizer employed virologists were quick to discount such an idea as "unlikely".

They claim that this amino acid sequence is too short for the immune system to meaningfully confuse it with this important placental protein. However unlikely, if this later proves true for some susceptible women, then that could cause infertility of an unspecified duration. Consider that scientific consensus is not 100 percent sure these similar amino acid sequences will cause Syncythin-1 antibodies to be produced. The role of retroviral proteins, especially syncytins, in the trophoblastic fusion

process and placental morphogenesis were only identified and hypothesized about 20years ago.60 There is still much to learn, and much we still do not know about similar amino acid sequences and their effect on human physiology. Thus, this issue warrants further research, and until then we should proceed with caution and assume that it may possibly cause public harm.

# **Adjuvants**

Adjuvants are immunostimulatory molecules administered together with the vaccine to help boost immune responses mainly by activating additional molecular receptors that predominantly recognize pathogens or danger signals. These pathways function primarily within the innate immune system, and each adjuvant generally has a different range of stimulation of these pathogen or danger receptors. While the vaccine goal is to stimulate recognition and response by lymphocytes, not innate cells, the activation of the innate immune cells is required to activate the lymphocytes to obtain both B and T-cell responses. Many adjuvants have previously failed in the clinic due to toxicity issues. These chemicals can have a wide range of compositions, including lipids, proteins, nucleic acids, and even inorganic material, such as aluminum salts. What they all have in common is that they hyper-stimulate receptors in immune cells and most do this through their cellular toxicity.

Pfizer/BioNTech and Moderna do not explicitly state the use of an adjuvant within their vaccines, but RNA already contains immunostimulatory properties and signals through pathogen recognition receptors. It remains to be seen whether the immunostimulation from

RNA is strong enough to confer full protection against SARS-CoV-2. There is also a possibility that the lipid nanoparticle carriers they utilize confer adjuvant properties themselves. Or for that matter, elicit an abnormal autoimmune reaction.

It is unknown if any future licensed COVID-19 mRNA vaccines will contain aluminum or something else as an adjuvant, as commonly used in other viral vaccines. Despite almost 90 years of widespread use of aluminum adjuvants, medical science's understanding of their mechanisms of action is still remarkably poor. There is also a concerning scarcity of data on toxicology and pharmacokinetics of these compounds. Despite this, the false notion that aluminium in vaccines is safe appears to be widely accepted. Experimental research clearly shows that aluminum adjuvants have a potential to induce serious immunological disorders in humans. Aluminum in adjuvant form carries a risk for autoimmunity, long-term brain inflammation, and associated neurological complications and may thus have profound and widespread adverse health consequences.

# Stability and Storage

These mRNA vaccines require cold storage to maintain the nanoparticles and to stop the mRNA from degrading. The Pfizer/BioNTech vaccine (BNT162b2) is to be stored at a temperature of -94 degrees Fahrenheit (-70 Celsius) and will last for only 24 hours at refrigerated temps between 35.6° and 46.4° Fahrenheit. It will be shipped on dry-ice (–80°C). The Moderna vaccine (mRNA-1273), must

be stored at -4° Fahrenheit (-20 C) and shipped at this –20°C temperature using gel packs.62

Thus, preserving this constant cold temperature is a major hurdle for the implementation of its vaccine marketing campaign, particularly the Pfizer/BioNTech vaccine. Given those constraints, analysts argued that Pfizer's vaccine could only be used at certain hospitals and clinics with the proper equipment, and would require intensive one-day vaccination events at such sites that would cover a fraction of the healthy population. Not only do most vaccination sites lack the freezing requirements needed, but also shipping companies are currently unable to ship mass quantities of ultracold vaccines. Pfizer has partnered with UPS to develop ultracold shipping containers that can hold the vaccine at the required temperature. The packages utilize cold-resistant glass vials to hold the vaccine and dry ice to maintain cold temperatures. Although this may seem like a sustainable solution, the US presently has a shortage of both dry-ice (due to a shortage in CO2) and cold-resistant glass.63 Mass shipping using these containers would cause a huge strain on the supply chain and likely would require investments of billions of dollars.64

# **Deployment**

Pfizer-BioNTech has said that they will be able to supply 50 million doses by the end of this year and around 1.3 billion by the end of 2021.

If licensed, Moderna has said it intends to provide the US government with 20 million doses by the end of this year, and manufacture between

500 million and one billion doses globally throughout 2021. There are currently more than 320 Covid-19 vaccine candidates in development. Several of them, including the Oxford/AstraZeneca vaccine, are emerging from phase III trials, so we can expect more announcements like this soon.

# No Liability Due to the PREP Act

With the upcoming SARS coronavirus-2 vaccines the vaccine industry is completely liability-free (not legally liable). The governmental nonliability guarantee for vaccine the manufacturers of current mRNA vaccines being implemented, or any future vaccines chosen to fast-track, comes out of the Emergency Use Authorization Authority (EUA Authority) that originated out of Project Bioshield. The Project Bioshield Act was an act passed by the United States Congress in 2004 calling for \$5 billion for purchasing vaccines that would be used in the event of a bioterrorist attack.

This was further defined by the PREP Act of 2005, the Public Readiness and Emergency Preparedness Act, which further granted the non-liability of vaccine manufacturers previously outlined in the 1986 Injury Compensation Program for childhood vaccines. On March 10, 2020, the Secretary invoked the PREP Act and determined that COVID-19 constitutes a public health emergency. Therefore, the HHS declaration authorizes PREP Act immunity for the "manufacture, testing, development, distribution, administration, and use" of covered countermeasures. An amendment to the PREP Act, which was updated in April65, stipulates that companies "cannot be sued for money

damages in court" over injuries caused by medical countermeasures for Covid-19. Such countermeasures include vaccines, therapeutics, and respiratory devices. The only exception to this immunity is if death or serious physical injury is caused by "willful misconduct." And even then, the people who are harmed will have to meet heightened standards for "willful misconduct" that are favorable to defendants.66

While people harmed by vaccines for other diseases are able to file claims with the National Vaccine Injury Compensation Program, which was established in 1986, the PREP Act now bars anyone who feels they were harmed by a vaccine for the coronavirus from using that program.

The PREP Act has allowed vaccine manufacturers unlimited freedom to create, develop, and market vaccines without any liability whatsoever. Manufacturers have been allowed to bypass animal studies and go directly to human trials. They also can add anything they deem important to the vaccine formula they choose - whether it be a known toxin or carcinogen. All liability is protected by the PREP Act, which means if anyone has an adverse event, or death caused by this vaccine there really is no recourse. This was put into the Federal Register in March of 2020 and does not expire till the end of 2024. So, anything that is developed over the next four years that has to do with a biological agent, such as a vaccine or drug or biotechnology, no matter how nefarious, is protected from liability under the umbrella of COVID-19.

#### Conclusion

The world, pushed by the pharmaceutical owned media, is clamoring for a safe, effective COVID-19 vaccine. Many laboratories and companies have scrambled to rapidly develop these vaccines, resulting in more than 200 vaccine candidates. Without proceeding with animal studies, many of these companies have entered human phase I, II and III clinical trials within a short period of 6 months. Pfizer/BioNTech and Moderna 'vaccines' moved quickly through human testing, without giving time for proper evaluation of earlier phases. They have not been approved or licensed by the U.S. Food and Drug Administration (FDA) ,but instead have received authorization for emergency use by the FDA under an Emergency Use Authorization (EUA) for use in individuals 16 years of age and older and are being injected into millions of people. Dangers arise due to the fast-tracking process that limits the time available for large-scale studies.

Owing to the accelerated development process, the interim data from ongoing clinical and preclinical vaccine studies are being published almost in real time. As a result, crucial information about the longevity and quality of vaccine-induced protective immunity is unavailable.

Fast-tracking leads companies to push out the vaccine before the results of a large-scale study show the safety and efficacy of the vaccine. Scientists and epidemiologists emphatically confirm that the primary focus of vaccine research is to prove it safe for a large population or group before being unleashed. The trials should offer clear datasets before releasing the vaccine to the public (millions if not billions of people). Without clear time-tested datasets of a large population, it is not possible to ensure that the vaccine is safe for most people in the country.

Pfizer released a Peer Review study entitled *Safety and Efficacy of the BNT162b2mRNA Covid-19 Vaccine*, recently published in the New England Journal of Medicine.67 In the Pfizer/BioNTech COVID-19 vaccine trials conducted in the United States, there were more allergic reactions reported in the vaccine group than in the placebo control group.68 While allergic reactions occurred in less than one percent of those receiving the COVID vaccine, it is important to note that individuals with a "history of severe adverse reaction associated with a vaccine and/ or severe allergic reaction (e.g., anaphylaxis) to any component of the study intervention(s)" were excluded from Pfizer's clinical trials.69, 70

Further testing and adequate time-testing may also identify specific health conditions, allergies, or related concerns of individuals that may not be qualified to take the vaccine. By fast-tracking the vaccine, the possibility of harm due to allergic reactions, autoimmune reactions, complications with an existing health condition, interactions with certain medications or other related concerns may increase when compared to a longer time frame for trials. In short, tests must prove that the vaccine is safe, which in vaccine time usually requires years rather than months.

Numbers reveal the death rate from COVID resumed to the normal flu death rate in early September 2020. Many scientists now view that the coronavirus pandemic is over. Therefore, a vaccine is no longer needed; it is totally unnecessary and comes with a potential danger. Perhaps the saddest part of this worldwide rush to the vaccine is seeing how little faith people have in their own immune systems.

Somehow the powers that should not be have managed to convince the majority of the people that the immune system is just a conspiracy theory, and rather than strengthening our own innate ability to heal and regenerate our bodies, we should give our faith into the hands of pharmaceutical corporations, who profit from sickness.

When we pause for just one moment to marvel the ability of your own skin to heal a wound or a bone to mend itself, we will realize that our bodies have their own bioregulatory intelligence. This organic living intelligence is far beyond the capacities of any nanotechnology or lab-created synthetic concoctions which merely try to mimic nature and its grand design. Our immune system and a healthy biological terrain are our best defense for pathogens and there are several proven ways to keep it active. The mineral zinc is important for numerous immunological enzymes and may be taken daily.

Vitamin D3 has been shown to be low or deficient in individuals that develop a serious coronavirus infection. Thus, taking vitamin D3 is preventive and may be taken daily to keep body levels therapeutic. Also, vitamin C has been extensively proven effective for infection protection. Getting fresh air and sunlight, staying active and well hydrated, and enjoying joyous social activities are all helpful in staying well.

Lastly, mRNA vaccines have never been licensed before, and now they are being administered to millions of people with no manufacturer liability. The public has become the testing ground for this new technology. If these coronavirus mRNA vaccines later prove to be harmful to fragile genetic cellular structures, then that cannot be undone.

Essentially, we need a much better understanding of their potential side effects, and more evidence of their long-term efficacy. Vaccine development takes time as the vaccines must not only be proven protective but also safe. Unlike other drugs that are delivered into sick patients, vaccines are administered into healthy patients and thus require very high safety margins. There is still a lot of research that should have been done around safety before mRNA vaccines become used on the public. Unfortunately, that is not what is happening now, and consequently this has a potential to turn into a disaster on a massive scale.

#### Note:

Vaccine providers are supposed to report adverse events that occur after vaccinations to VAERS but vaccinated persons who experienced the reaction or a family member also can file a report if a health care provider does not do it.

According to one government funded study in 2011, fewer than one percent of all vaccine reactions are reported to VAERS.

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

#### References

- Takano, Tomomi, Shinji Yamada, Tomoyoshi Doki, and Tsutomu Hohdatsu. "Pathogenesis of oral type I feline infectious peritonitis virus (FIPV) infection: Antibody-dependent enhancement infection of cats with type I FIPV via the oral route." Journal of Veterinary Medical Science (2019): 18-0702. <a href="https://www.jstage.jst.go.jp/article/jvms/advpub/0/advpub\_18-0702/">https://www.jstage.jst.go.jp/article/jvms/advpub/0/advpub\_18-0702/</a> pdf
- Czub, Markus, Hana Weingartl, Stefanie Czub, Runtao He, and Jingxin Cao. "Evaluation of modified vaccinia virus Ankara based recombinant SARS vaccine in ferrets." *Vaccine* 23, no. 17-18 (2005): 2273-2279. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7115540/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7115540/</a>
- Fett, Craig, Marta L. DeDiego, Jose A. Regla-Nava, Luis Enjuanes, and Stanley Perlman. "Complete protection against severe acute respiratory syndrome coronavirus-mediated lethal respiratory disease in aged mice by immunization with a mouseadapted virus lacking E protein." *Journal of virology* 87, no. 12 (2013): 6551-6559. <a href="https://jvi.asm.org/content/jvi/87/12/6551.full.pdf">https://jvi.asm.org/content/jvi/87/12/6551.full.pdf</a>
- . Wang, Qidi, Lianfeng Zhang, Kazuhiko Kuwahara, Li Li, Zijie Liu, Taisheng Li, Hua Zhu et al. "Immunodominant SARS coronavirus epitopes in humans elicited both enhancing and neutralizing effects on infection in non-human primates." *ACS infectious*

diseases 2, no. 5 (2016): 361-376. <a href="https://pubs.acs.org/doi/full/10.1021/acsinfecdis.6b00006">https://pubs.acs.org/doi/full/10.1021/acsinfecdis.6b00006</a>

- Pedersen, Niels C. "An update on feline infectious peritonitis: virology and immunopathogenesis." *The Veterinary Journal* 201, no. 2 (2014): 123-132. <a href="https://www.sciencedirect.com/science/article/pii/S1090023314001786">https://www.sciencedirect.com/science/article/pii/S1090023314001786</a>
- Kam, Yiu Wing, François Kien, Anjeanette Roberts, Yan Chung Cheung, Elaine W. Lamirande, Leatrice Vogel, Shui Ling Chu et al. "Antibodies against trimeric S glycoprotein protect hamsters against SARS-CoV challenge despite their capacity to mediate FcγRII-dependent entry into B cells in vitro." *Vaccine* 25, no. 4 (2007): 729-740. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7115629/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7115629/</a>
- Agnihothram, Alan Whitmore, Martin Ferris, William Funkhouser et al. "A double-inactivated severe acute respiratory syndrome coronavirus vaccine provides incomplete protection in mice and induces increased eosinophilic proinflammatory pulmonary response upon challenge." *Journal of virology* 85, no. 23 (2011): 12201-12215. <a href="https://jvi.asm.org/content/jvi/85/23/12201.full.pdf">https://jvi.asm.org/content/jvi/85/23/12201.full.pdf</a>
- . Tirado, S. M. C., & Yoon, K. J. (2003). Antibody-dependent enhancement of virus infection and disease. *Viral immunology*, *16*(1), 69-86. <a href="https://www.liebertpub.com/doi/abs/">https://www.liebertpub.com/doi/abs/</a>

#### 10.1089/088282403763635465

- Takada, Ayato, and Yoshihiro Kawaoka. "Antibody-dependent enhancement of viral infection: molecular mechanisms and in vivo implications." Reviews in medical virology 13, no. 6 (2003): 387-398. https://onlinelibrary.wiley.com/doi/abs/10.1002/rmv.405
- Wang, Sheng-Fan, Sung-Pin Tseng, Chia-Hung Yen, Jyh-Yuan Yang, Ching-Han Tsao, Chun-Wei Shen, Kuan-Hsuan Chen et al. "Antibody-dependent SARS coronavirus infection is mediated by antibodies against spike proteins." *Biochemical and biophysical research communications* 451, no. 2 (2014): 208-214. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7092860/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7092860/</a>
- Wan, Yushun, Jian Shang, Shihui Sun, Wanbo Tai, Jing Chen, Qibin Geng, Lei He et al. "Molecular mechanism for antibodydependent enhancement of coronavirus entry." *Journal of virology* 94, no. 5 (2020). https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC7022351/
- Dutry, Isabelle, Hui-ling Yen, Horace Lee, Malik Peiris, and Martial Jaume. "Antibody-dependent enhancement (ADE) of infection and its possible role in the pathogenesis of influenza." In BMC proceedings, vol. 5, no. 1, p. P62. BioMed Central, 2011. <a href="https://bmcproc.biomedcentral.com/track/pdf/10.1186/1753-6561-5-S1-P62?site=http://bmcproc.biomedcentral.com/">https://bmcproc.biomedcentral.com/track/pdf/10.1186/1753-6561-5-S1-P62?site=http://bmcproc.biomedcentral.com/</a>

- Ruckwardt, Tracy J., Kaitlyn M. Morabito, and Barney S. Graham.
  "Immunological lessons from respiratory syncytial virus vaccine development." *Immunity* 51, no. 3 (2019): 429-442.+ https://www.sciencedirect.com/science/article/pii/S1074761319303334
- Dejnirattisai, Wanwisa, Amonrat Jumnainsong, Naruthai Onsirisakul, Patricia Fitton, Sirijitt Vasanawathana, Wannee Limpitikul, Chunya Puttikhunt et al. "Cross-reacting antibodies enhance dengue virus infection in humans." Science 328, no. 5979 (2010): 745-748. <a href="https://europepmc.org/article/PMC/3837288">https://europepmc.org/article/PMC/3837288</a>
- Beck, Zoltán, Zoltán Prohászka, and George Füst. "Traitors of the immune system—enhancing antibodies in HIV infection: their possible implication in HIV vaccine development." *Vaccine* 26, no. 24 (2008): 3078-3085.
- . Burke, Donald S. "Human HIV vaccine trials: does antibody-dependent enhancement pose a genuine risk?." Perspectives in Biology and Medicine 35, no. 4 (1992): 511-530. <a href="https://muse.jhu.edu/article/459161/pdf">https://muse.jhu.edu/article/459161/pdf</a>
- . Takada, Ayato, Heinz Feldmann, Thomas G. Ksiazek, and Yoshihiro Kawaoka. "Antibody-dependent enhancement of Ebola virus infection." Journal of virology 77, no. 13 (2003): 7539-7544. <a href="https://jvi.asm.org/content/jvi/77/13/7539.full.pdf">https://jvi.asm.org/content/jvi/77/13/7539.full.pdf</a>
- . Takada, Ayato, Shinji Watanabe, Katsunori Okazaki, Hiroshi Kida,

and Yoshihiro Kawaoka. "Infectivity-enhancing antibodies to Ebola virus glycoprotein." *Journal of virology* 75, no. 5 (2001): 2324-2330.

- Gauger PC, Vincent AL, Loving CL, Lager KM, Janke BH, Kehrli ME Jr., and Roth JA: Enhanced pneumonia and disease in pigs vaccinated with an inactivated human-like (delta-cluster) H1N2 vaccine and challenged with pandemic 2009 H1N1 influenza virus. Vaccine 2011;29:2712–2719. <a href="https://lib.dr.iastate.edu/cgi/viewcontent.cgi?article=1075&context=vmpm\_pubs">https://lib.dr.iastate.edu/cgi/viewcontent.cgi?article=1075&context=vmpm\_pubs</a>
- Rajão, Daniela S., Hongjun Chen, Daniel R. Perez, Matthew R. Sandbulte, Phillip C. Gauger, Crystal L. Loving, G. Dennis Shanks, and Amy Vincent. "Vaccine-associated enhanced respiratory disease is influenced by haemagglutinin and neuraminidase in whole inactivated influenza virus vaccines." Journal of General Virology 97, no. 7 (2016): 1489-1499. <a href="https://www.microbiologyresearch.org/docserver/fulltext/jgv/97/7/1489\_vir000468.pdf?">https://www.microbiologyresearch.org/docserver/fulltext/jgv/97/7/1489\_vir000468.pdf?</a>
  <a href="mailto:expires=1591728632&id=id&accname=guest&checksum=5007EAF2D1FCFBE1C2DD06ED7D1C8FFE">expires=1591728632&id=id&accname=guest&checksum=5007EAF2D1FCFBE1C2DD06ED7D1C8FFE</a>
- Olsen, CHRISTOPHER W., W. V. Corapi, C. K. Ngichabe, J. D. Baines, and F. W. Scott. "Monoclonal antibodies to the spike protein of feline infectious peritonitis virus mediate antibody-dependent enhancement of infection of feline macrophages."

  Journal of virology 66, no. 2 (1992): 956-965. https://jvi.asm.org/content/jvi/66/2/956.full.pdf

Wang, Sheng-Fan, Sung-Pin Tseng, Chia-Hung Yen, Jyh-Yuan Yang, Ching-Han Tsao, Chun-Wei Shen, Kuan-Hsuan Chen et al. "Antibody-dependent SARS coronavirus infection is mediated by antibodies against spike proteins." *Biochemical and biophysical research communications* 451, no. 2 (2014): 208-214. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7092860/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7092860/</a>

- Wan, Yushun, Jian Shang, Shihui Sun, Wanbo Tai, Jing Chen, Qibin Geng, Lei He et al. "Molecular mechanism for antibodydependent enhancement of coronavirus entry." *Journal of virology* 94, no. 5 (2020). <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/">https://www.ncbi.nlm.nih.gov/pmc/articles/</a> PMC7022351/
- Jaume, Martial, Ming S. Yip, Chung Y. Cheung, Hiu L. Leung, Ping H. Li, Francois Kien, Isabelle Dutry et al. "Anti-severe acute respiratory syndrome coronavirus spike antibodies trigger infection of human immune cells via a pH-and cysteine proteaseindependent FcγR pathway." *Journal of virology* 85, no. 20 (2011): 10582-10597. <a href="https://jvi.asm.org/content/jvi/85/20/10582.full.pdf">https://jvi.asm.org/content/jvi/85/20/10582.full.pdf</a>
- Iwasaki, Akiko, and Yexin Yang. "The potential danger of suboptimal antibody responses in COVID-19." *Nature Reviews Immunology* (2020): 1-3. <a href="https://www.nature.com/articles/s41577-020-0321-6?fbclid=lwAR2OHhAhzFzJpqZOEI\_ifMLBpihW-beWYoGQ0L4XJ5cDQRpleOQ5kQ9IH28">https://www.nature.com/articles/s41577-020-0321-6?fbclid=lwAR2OHhAhzFzJpqZOEI\_ifMLBpihW-beWYoGQ0L4XJ5cDQRpleOQ5kQ9IH28</a>
- https://www.chelseagreen.com/product/corona-false-alarm/

Pulendran, Bali, and Rafi Ahmed. "Translating innate immunity into immunological memory: implications for vaccine development." *Cell* 124, no. 4 (2006): 849-863. <a href="https://www.sciencedirect.com/science/article/pii/S0092867406001942">https://www.sciencedirect.com/science/article/pii/S0092867406001942</a>

- Baxter, David. "Active and passive immunity, vaccine types, excipients and licensing." *Occupational Medicine* 57, no. 8 (2007): 552-556. <a href="https://academic.oup.com/occmed/article/57/8/552/1474357">https://academic.oup.com/occmed/article/57/8/552/1474357</a>
- . Sahin, Ugur, Katalin Karikó, and Özlem Türeci. "mRNA-based therapeutics—developing a new class of drugs." *Nature reviews Drug discovery* 13, no. 10 (2014): 759-780. <a href="https://www.nature.com/articles/nrd4278?cacheBust=1508171532658">https://www.nature.com/articles/nrd4278?cacheBust=1508171532658</a>
- Minor, Philip D. "Live attenuated vaccines: Historical successes and current challenges." *Virology* 479 (2015): 379-392. <a href="https://www.sciencedirect.com/science/article/pii/S004268221500172">https://www.sciencedirect.com/science/article/pii/S004268221500172</a>
  Lundstrom, Kenneth. "Latest development on RNA-based drugs and vaccines." *Future science OA* 4, no. 5 (2018): FSO300. <a href="https://www.future-science.com/doi/full/10.4155/fsoa-2017-0151?">https://www.future-science.com/doi/full/10.4155/fsoa-2017-0151?</a>
  <a href="https://www.future-science.com/doi/full/10.4155/fsoa-2017-0151?">https://www.future-science.com/doi/full/10.4155/fsoa-2017-0151?</a>
- Sahin, Ugur, Katalin Karikó, and Özlem Türeci. "mRNA-based therapeutics—developing a new class of drugs." *Nature reviews Drug discovery* 13, no. 10 (2014): 759-780. <a href="https://">https://</a>

#### www.nature.com/articles/nrd4278?cacheBust=1508171532658

- . Scorza, Francesco Berlanda, and Norbert Pardi. "New kids on the block: RNA-based influenza virus vaccines." *Vaccines* 6, no. 2 (2018): 20. <a href="https://www.mdpi.com/2076-393X/6/2/20/htm">https://www.mdpi.com/2076-393X/6/2/20/htm</a>
- Brito, Luis A., Sushma Kommareddy, Domenico Maione, Yasushi Uematsu, Cinzia Giovani, Francesco Berlanda Scorza, Gillis R. Otten et al. "Self-amplifying mRNA vaccines." In *Advances in genetics*, vol. 89, pp. 179-233. Academic Press, 2015. <a href="https://www.sciencedirect.com/science/article/abs/pii/">https://www.sciencedirect.com/science/article/abs/pii/</a>
  S0065266014000066
- Pardi, Norbert, Michael J. Hogan, Frederick W. Porter, and Drew Weissman. "mRNA vaccines—a new era in vaccinology." *Nature reviews Drug discovery* 17, no. 4 (2018): 261. <a href="https://www.nature.com/articles/nrd.2017.243">https://www.nature.com/articles/nrd.2017.243</a>.
- Pardi, Norbert, and Drew Weissman. "Measuring the Adjuvant Activity of RNA Vaccines." In *RNA Vaccines*, pp. 143-153. Humana Press, New York, NY, 2017. <a href="https://link.springer.com/protocol/">https://link.springer.com/protocol/</a>
  10.1007/978-1-4939-6481-9 8
- Holtkamp, S. et al. (2006) Modification of antigen-encoding RNA increases stability, translational efficacy, and T-cell stimulatory capacity of dendritic cells. *Blood* **108**, 4009–4017. <a href="https://pdfs.semanticscholar.org/">https://pdfs.semanticscholar.org/</a>

# 5a61/5fed2165a18d63d5718cc945fb163845057b.pdf

- . Geall, A.J. et al. (2012) Nonviral delivery of self-amplifying RNA vaccines. *Proc. Natl Acad. Sci. USA* **109**, 14604–14609. <a href="https://www.pnas.org/content/pnas/109/36/14604.full.pdf">https://www.pnas.org/content/pnas/109/36/14604.full.pdf</a>
- Lutz J. et al. (2017) Unmodified mRNA in LNPs constitutes a competitive technology for prophylactic vaccines. NPJ Vaccines (2017) 2, 29. https://www.nature.com/articles/s41541-017-0032-6
- Probst, Jochen, Sonja Brechtel, Birgit Scheel, Ingmar Hoerr, Günther Jung, Hans-Georg Rammensee, and Steve Pascolo.

  "Characterization of the ribonuclease activity on the skin surface."

  Genetic vaccines and therapy 4, no. 1 (2006): 4. <a href="https://link.springer.com/article/10.1186/1479-0556-4-4">https://link.springer.com/article/10.1186/1479-0556-4-4</a>
- Yang, Qi, and Samuel K. Lai. "Anti-PEG immunity: emergence, characteristics, and unaddressed questions." *Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology* 7, no. 5 (2015): 655-677. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4515207/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4515207/</a>
- Garay, Ricardo P., Raafat El-Gewely, Jonathan K. Armstrong, George Garratty, and Pascal Richette. "Antibodies against polyethylene glycol in healthy subjects and in patients treated with PEG-conjugated agents." (2012): 1319-1323. <a href="https://www.tandfonline.com/doi/pdf/10.1517/17425247.2012.720969">https://www.tandfonline.com/doi/pdf/10.1517/17425247.2012.720969</a>

Zhang, Peng, Fang Sun, Sijun Liu, and Shaoyi Jiang. "Anti-PEG antibodies in the clinic: Current issues and beyond PEGylation." *Journal of Controlled Release* 244 (2016): 184-193. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5747248/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5747248/</a>

- Ganson, Nancy J., Thomas J. Povsic, Bruce A. Sullenger, John H. Alexander, Steven L. Zelenkofske, Jeffrey M. Sailstad, Christopher P. Rusconi, and Michael S. Hershfield. "Pre-existing anti—polyethylene glycol antibody linked to first-exposure allergic reactions to pegnivacogin, a PEGylated RNA aptamer." *Journal of Allergy and Clinical Immunology* 137, no. 5 (2016): 1610-1613. <a href="https://www.jacionline.org/article/S0091-6749(15)01667-X/fulltext">https://www.jacionline.org/article/S0091-6749(15)01667-X/fulltext</a>
- Richter, Ary Wolfgang, and Eva Åkerblom. "Polyethylene glycol reactive antibodies in man: titer distribution in allergic patients treated with monomethoxy polyethylene glycol modified allergens or placebo, and in healthy blood donors." *International Archives of Allergy and Immunology* 74, no. 1 (1984): 36-39. <a href="https://www.karger.com/Article/Abstract/233512">https://www.karger.com/Article/Abstract/233512</a>
- Ishida, Tatsuhiro, XinYu Wang, Taro Shimizu, Kosuke Nawata, and Hiroshi Kiwada. "PEGylated liposomes elicit an anti-PEG IgM response in a T cell-independent manner." *Journal of controlled release* 122, no. 3 (2007): 349-355. <a href="https://www.sciencedirect.com/science/article/abs/pii/S0168365907002428">https://www.sciencedirect.com/science/article/abs/pii/S0168365907002428</a>
- . Yang, Qi, Timothy M. Jacobs, Justin D. McCallen, Dominic T.

Moore, Justin T. Huckaby, Jasmine N. Edelstein, and Samuel K. Lai. "Analysis of pre-existing IgG and IgM antibodies against polyethylene glycol (PEG) in the general population." *Analytical chemistry* 88, no. 23 (2016): 11804-11812. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6512330/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6512330/</a>

- Rauch, Susanne, Edith Jasny, Kim E. Schmidt, and Benjamin Petsch. "New vaccine technologies to combat outbreak situations." Frontiers in immunology 9 (2018): 1963. https://www.frontiersin.org/articles/10.3389/fimmu.2018.01963/full
- . <a href="https://arcturusrx.com/proprietary-technologies/">https://arcturusrx.com/proprietary-technologies/</a>
- Pardi, Norbert, Michael J. Hogan, Frederick W. Porter, and Drew Weissman. "mRNA vaccines—a new era in vaccinology." *Nature reviews Drug discovery* 17, no. 4 (2018): 261. <a href="https://www.nature.com/articles/nrd.2017.243">https://www.nature.com/articles/nrd.2017.243</a>.

Fischer, Silvia, Tibo Gerriets, Carina Wessels, Maureen Walberer, Sawa Kostin, Erwin Stolz, Kirila Zheleva, Andreas Hocke, Stefan Hippenstiel, and Klaus T. Preissner. "Extracellular RNA mediates endothelial-cell permeability via vascular endothelial growth factor." *Blood* 110, no. 7 (2007): 2457-2465. <a href="https://www.researchgate.net/profile/Andreas Hocke/publication/">https://www.researchgate.net/profile/Andreas Hocke/publication/</a>

6259977 Extracellular RNA Mediates Endothelial Cell Permeab ility via Vascular Endothelial Growth Factor/links/
00463523c326a4024e000000/Extracellular-RNA-MediatesEndothelial-Cell-Permeability-via-Vascular-Endothelial-GrowthFactor.pdf

Kannemeier, Christian, Aya Shibamiya, Fumie Nakazawa, Heidi Trusheim, Clemens Ruppert, Philipp Markart, Yutong Song et al. "Extracellular RNA constitutes a natural procoagulant cofactor in blood coagulation." *Proceedings of the National Academy of Sciences* 104, no. 15 (2007): 6388-6393. <a href="https://www.pnas.org/content/pnas/104/15/6388.full.pdf">https://www.pnas.org/content/pnas/104/15/6388.full.pdf</a>

- Tusup, Marina, Thomas Kundig, and Steve Pascolo.
   "Epitranscriptomics of cancer." World Journal of Clinical Oncology
   9, no. 3 (2018): 42. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/">https://www.ncbi.nlm.nih.gov/pmc/articles/</a>
   PMC5997933/
- Hsu, Phillip J., Hailing Shi, and Chuan He. "Epitranscriptomic influences on development and disease." *Genome biology* 18, no. 1 (2017): 197. <a href="https://genomebiology.biomedcentral.com/articles/10.1186/s13059-017-1336-6?optln=true">https://genomebiology.biomedcentral.com/articles/10.1186/s13059-017-1336-6?optln=true</a>
  Lian, Hao, Qin-Hua Wang, Chang-Bin Zhu, Jie Ma, and Wei-Lin Jin. "Deciphering the epitranscriptome in cancer." *Trends in cancer* 4, no. 3 (2018): 207-221.
- Dinescu, Sorina, Simona Ignat, Andreea Daniela Lazar, Carolina Constantin, Monica Neagu, and Marieta Costache.

  "Epitranscriptomic signatures in IncRNAs and their possible roles in cancer." *Genes* 10, no. 1 (2019): 52.

  <a href="https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?">https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?</a>
  <a href="mailto:setid=908ecbe7-2f1b-42dd-94bf-f917ec3c5af8">setid=908ecbe7-2f1b-42dd-94bf-f917ec3c5af8</a>
  <a href="https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker">https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker</a>

Frank, Hans-George, Patrick Bose, Andrea Albieri-Borges,
Marcus Borges, Alexandra Greindl, Josepf Neulen, Andy JG
Pötgens, and Peter Kaufmann. "Evaluation of fusogenic
trophoblast surface epitopes as targets for immune contraception."

Contraception 71, no. 4 (2005): 282-293. https://
www.sciencedirect.com/science/article/abs/pii/
S0010782405000181

- Mi, Sha, Xinhua Lee, Xiang-ping Li, Geertruida M. Veldman,
  Heather Finnerty, Lisa Racie, Edward LaVallie et al. "Syncytin is a
  captive retroviral envelope protein involved in human placental
  morphogenesis." *Nature* 403, no. 6771 (2000): 785-789.

  <a href="https://www.biologicalmedicineinstitute.com/articles-aluminum1">https://www.biologicalmedicineinstitute.com/articles-aluminum1</a>
- Jones, Kathryn L., Debbie Drane, and Eric J. Gowans. "Long-term storage of DNA-free RNA for use in vaccine studies." *Biotechniques* 43, no. 5 (2007): 675-681. <a href="https://www.future-science.com/doi/pdf/10.2144/000112593">https://www.future-science.com/doi/pdf/10.2144/000112593</a>
- Gelles D. How to Ship a Vaccine at -80°C, and Other Obstacles in the Covid Fight. The New York Times [Internet] 2020 Sep 19 [Cited 2020 Oct 11]. Available from:
- https://www.nytimes.com/2020/09/18/business/coronavirus-covid-vaccine-cold-frozen-logistics.html
  Brown, T. T. H. "Pfizer's Major Setback in the COVID-19 Vaccine Race." <a href="http://ursa.browntth.com/the-blog/pfizers-major-setback-in-the-covid-19-vaccine-race">http://ursa.browntth.com/the-blog/pfizers-major-setback-in-the-covid-19-vaccine-race</a>

Federal Register :: Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

.

Polack, Fernando P., Stephen J. Thomas, Nicholas Kitchin, Judith Absalon, Alejandra Gurtman, Stephen Lockhart, John L. Perez et al. "Safety and efficacy of the BNT162b2 mRNA covid-19 vaccine." *New England Journal of Medicine* (2020). <a href="https://www.nejm.org/doi/full/10.1056/NEJMoa2034577">https://www.nejm.org/doi/full/10.1056/NEJMoa2034577</a>

.

FDA. FDA Briefing Document: Pfizer-BioNTech COVID-19

Vaccine. VRBPAC Committee Meeting Dec. 10, 2020.

- Pfizer. Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Adults. Exclusion Criteria. Sept. 28, 2020.
- Weintraub K. 'Very inconsistent': 2 allergic reactions in the UK to COVID-19 vaccine puzzle researchers. *USA Today* Dec. 9, 2020.

https://www.biologicalmedicineinstitute.com/post/covid-19-

mrna-vaccines