The Pfizer mRNA vaccine: pharmacokinetics and toxicity

Michael Palmer, MD and Sucharit Bhakdi, MD

July 23rd, 2021

Abstract

We summarize the findings of an animal study which Pfizer submitted to the Japanese health authorities in 2020, and which pertained to the distribution and elimination of a model mRNA vaccine. We show that this study clearly presaged grave risks of blood clotting and other adverse effects. The failure to monitor and assess these risks in the subsequent clinical trials, and the grossly negligent review process in conjunction with the emergency use authorizations, have predictably resulted in an unprecedented medical disaster.

1 Introduction and background

As with any drug, a key consideration for the toxicity of the COVID mRNA vaccines is where exactly in the body they end up, and for how long they will stay there. Such questions, which are the subject of *pharmacokinetics*, are usually thoroughly investigated and during drug development. Initial studies on pharmacokinetics and also on toxicity are carried out in animals. If the outcome is favourable, similar experiments will be performed on a small number of human volunteers. Only after such preliminary studies have been successfully concluded will proper clinical trials be approved, which will then determine whether the drug or vaccine in question has the desired clinical efficacy.

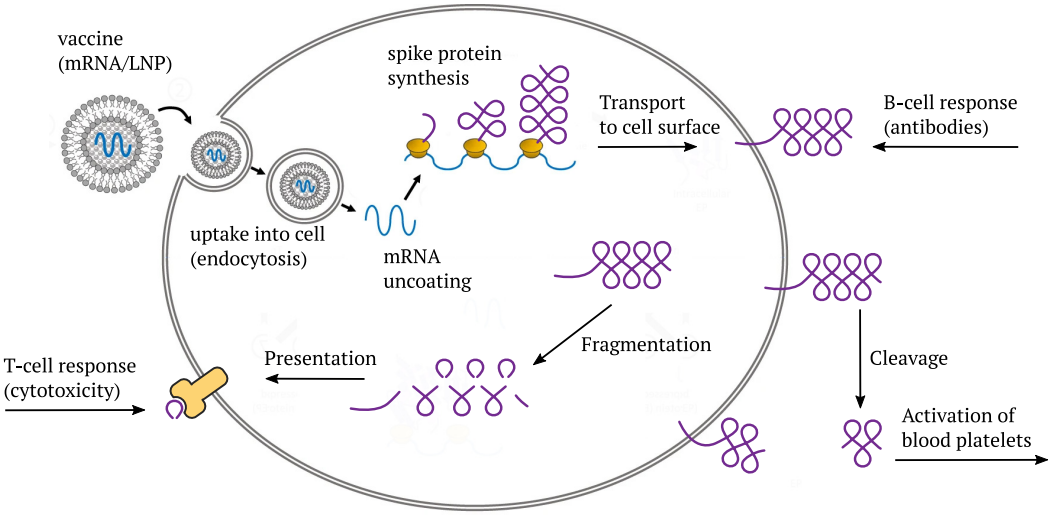
Because of the officially sanctioned haste and systematic gross negligence in the development and approval of the COVID-19 vaccines, our knowledge of their pharmacokinetics is sketchy. The only somewhat detailed animal study that has reached the public pertains to the Pfizer vaccine [1, 2]. These data were publicized after Pfizer had filed them with the Health authorities in Japan when applying for emergency use authorization of its vaccine in that country.[1] These data pertained in particular to the distribution of the vaccine within the body after injection and to its elimination from the body. Even though far from being comprehensive or even adequate, this document has rather far-reaching implications: it shows that Pfizer— as well as the authorities that were apprised of these data— must have recognized the grave risks of adverse events after vaccination even before the onset of clinical trials. Nevertheless, Pfizer's own clinical trials failed to monitor any of the clinical

[1] The same data may also have been filed in the U.S. and other wester countries, but the FDA and the corresponding health regulators did not release them to the public.

risks that were clearly evident from these data, and the regulatory authorities failed to enforce proper standards of oversight. This dual failure has caused the most grievous harm to the public.

Before we discuss this study and its implications in detail, we will briefly review how the Pfizer mRNA vaccine works. These explanations also apply to the Moderna mRNA vaccine, whereas the AstraZeneca and the Johnson & Johnson vaccines differ in some aspects.

1.1 How the mRNA COVID vaccines work



The Pfizer and Moderna mRNA vaccines consist of a synthetic messenger RNA (mRNA) that encodes the SARS-CoV-2 "spike protein," which normally is found on the surface of the coronavirus particles. This mRNA is coated with a mixture of synthetic *lipids* (fat-like molecules) that protect it during transport within the body, and which also facilitate its uptake into the target cells through *endocytosis*.

After the vaccine has entered a cell, it initially finds itself enclosed by a membrane vesicle—a little bubble that was pinched off from the cell membrane. The subsequent accumulation of acid inside this bubble causes the lipids to be stripped off, and the mRNA to be released into the cytosol (the intracellular fluid); this release step is facilitated by the cationic lipid ALC-0315 (see later). The mRNA then binds to *ribosomes*—the cell's little protein factories—and induces the synthesis of the actual spike protein molecules. Most of the spike protein molecules will then be transported to the cell surface.

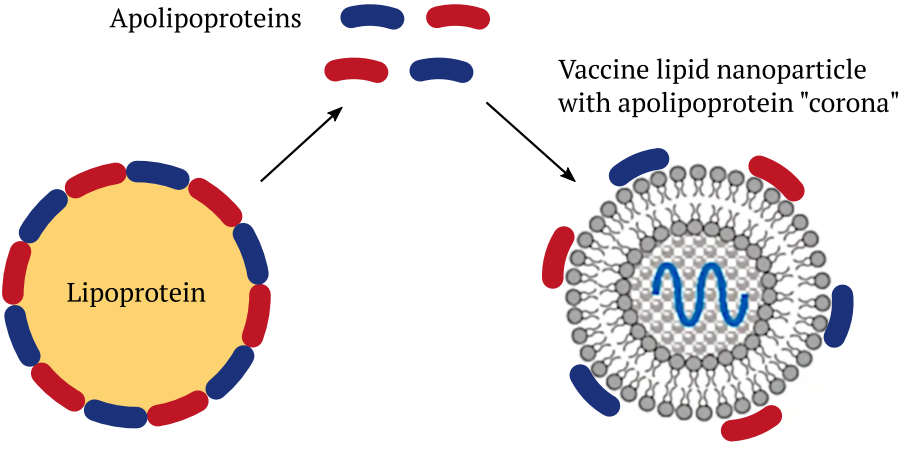
Once it appears there, it will be recognized by B-lymphocytes (B-cells), which will then start making antibodies to it.[2] Furthermore, some part of the spike protein can also be cleaved off by proteases on the cell surface and released from the cell. If this happens within the circulation, the released fragment—referred to as *S1*—can bind to blood platelets (thrombocytes) and activate them. In this manner, the spike protein directly promotes blood clotting.

[2] B-cell activation involves additional steps and auxiliary cells that are here omitted for simplicity.

As with any protein that is synthesized within the cell, a small number of molecules will undergo fragmentation, and the fragments will be presented on the cell surface in association with specific (HLA-) carrier proteins. The purpose of this mechanism is immune surveillance—as soon as fragments show up of some protein which the immune system does not recognize as "self," an immune response will be mounted against that protein and against the cells that produce it. This response is mediated by cytotoxic T-lymphocytes (CTLs, T-killer cells).

In mounting its cytotoxic response, the immune system will not distinguish between a true virus infection and the expression of an mRNA vaccine—as long as the spike protein fragments appear on the cell, the killer cells will be on the march. If the vaccine is expressed in the cells that line the blood vessels—the *endothelial* cells—the vascular lesion caused by the immune attack will again set off blood clotting. Thus, we have at least two distinct paths toward blood clotting after vaccination.

1.2 The lipid-coated mRNA vaccines acquire an apolipoprotein "corona"



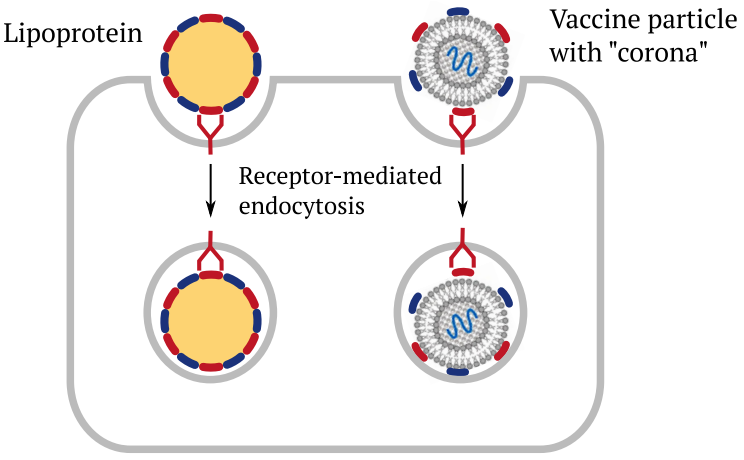
Lipoprotein particles occur naturally in the bloodstream and within the tissues of our body. They consist of a core of lipids that is surrounded with a shell of proteins called *apolipoproteins*. Their purpose is to transport lipids such as cholesterol and triacylglycerol (regular fat) between organs. For example, a specific type of lipoprotein called *chylomicrons* transports dietary fats after they have been taken up in the small intestine. Other lipoproteins called VLDL and LDL distribute fats that have been synthesized in the liver to other organs and tissues.

The various apolipoproteins that encase the lipoproteins stabilize the particles, and they also serve as "address tags" that bind to receptor molecules on cell surfaces. This interaction will trigger the uptake of the lipoproteins into those cells. Artificial lipid nanoparticles (LNPs) like those used in the COVID mRNA vaccines can acquire a shell—a "corona"—of the body's own apolipoprotein molecules [3]. This enables these vaccines to be taken up into the cells of our body, too.

The liver has a central place in lipid and lipoprotein metabolic turnover. Accordingly, liver cells are rich in specific surface receptor molecules which mediate

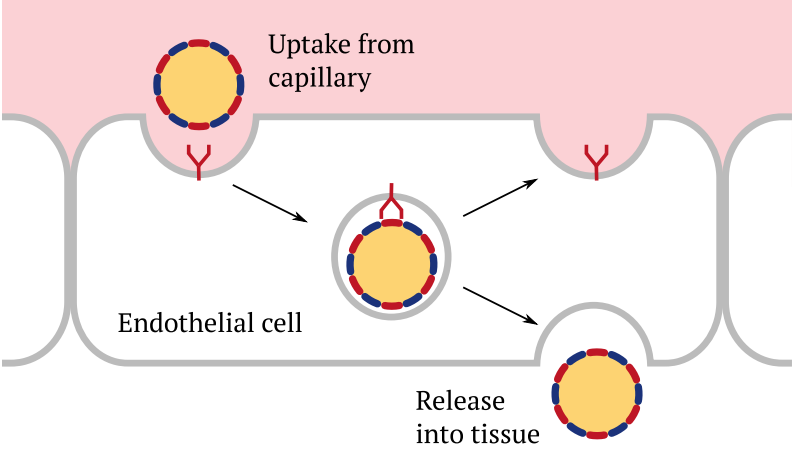
lipoprotein uptake, suggesting that they will efficiently take up LNPs decorated with apolipoproteins also. This is indeed the case. However, other organs have high rates of lipoprotein uptake, too, and they must therefore be expected to accumulate the apolipoprotein-decorated vaccine LNPs as well.

1.3 Receptor-mediated cellular uptake of lipoproteins and of vaccines



This slide illustrates the role of cellular receptors and the apolipoproteins in facilitating the uptake of vaccines into cells through endocytosis. They bind to the same cellular receptors as the regular lipoprotein particles do, and they subsequently get taken up in the same manner. The subsequent events—release of the mRNA and protein synthesis—have already been discussed above.

1.4 Transcytosis of lipoproteins from the bloodstream into the tissues



All substrate exchange between the tissues and the bloodstream occurs in the capillaries. In these finest of all blood vessels, the blood is separated from the extracellular matrix of the tissues by only one cellular layer—namely, the endothelial cells. The capillary wall permits free passage only to small molecules such as for example

blood sugar (glucose) or amino acids. The lipoproteins, which are far larger, must be transported across the capillary wall by *transcytosis*. In this two-stage process, endocytosis on one side of the cell is followed by *exocytosis*, that is, by release of the particles, which occurs on the other side.

While this figure shows transcytosis from the bloodstream to the tissue, the process actually works in both directions. In this manner, cells in the tissues can avail themselves of cholesterol carried by circulating LDL, but they can also return surplus cholesterol through the bloodstream to the liver via other lipoproteins (HDL).

Transcytosis will also apply to the "corona"-decorated vaccine LNPs and enable them to reach the tissues in various organs. Reverse transcytosis of vaccine might contribute to its uptake from the muscle tissue into the circulation after injection (see below).

2 The Pfizer vaccine pharmacokinetics study on rats

- A "model vaccine" was used—same LNPs, different mRNA (coding for luciferase)
- Cholesterol contained in the LNPs was labeled with radioactivity (^{3}H) for tracing
- The distribution of the lipid between different organs was measured at various time points following intramuscular injection

This is the key experiment in Pfizer's animal study [1]. The technical approach used here is quite common, since radioactivity can be very sensitively and accurately measured. The radioactively labeled vaccine preparation was injected into rats. The animals were "sacrificed" (cut up) at various time points after the injection, and the amount of radioactivity in different organs was measured.

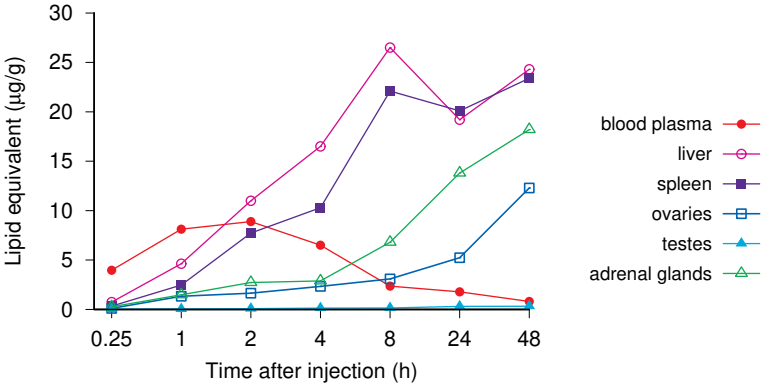
The model protein used in this study was a firefly protein called *luciferase*. This is the very protein that permits fireflies to glow in the dark. When the rats' body cells take up the mRNA that encodes luciferase and then synthesize the protein, they, too, will begin to glow in the dark. Light, like radioactivity, is convenient to measure; the more light that emanates from a given tissue, the more mRNA uptake and protein synthesis have occurred.[3] Therefore, between the radiolabel on the lipid and the luminescence elicited by luciferase, it was possible to determine both the distribution of the model vaccine within the body and its biological activity.

2.1 Key data from the lipid distribution study

The first thing to note is that the labeled lipid shows up in the blood plasma after a very short time. The highest plasma level is reached at two hours after the injection; however, even after only 15 minutes (0.25 hours) the level already reaches almost half of that maximal value. Reverse transcytosis might in part account for this rapid uptake process. A more important factor may be drainage of tissue fluid

[3] To generate light, luciferase also requires a specific small-molecule substrate named luciferin and adenosine triphosphate (ATP). The luminescence assay is therefore more complex and less quantitatively accurate than measurements of radioactivity.

through the lymphatic vessels into the bloodstream. Lymphatic drainage will likely be accelerated by the acute release of inflammatory mediators within the muscle tissue.



As the blood plasma level drops off, the activity rises in several other organs. The fastest and highest rise is observed in the liver and the spleen. Both of these organs are rich in *macrophages*, a cell type that is in charge of clearing particles such as microbes or the fragments of decayed cells from the bloodstream. Macrophages are also numerous in the bone marrow, where the vaccine reaches somewhat lower but still substantial levels (not shown).

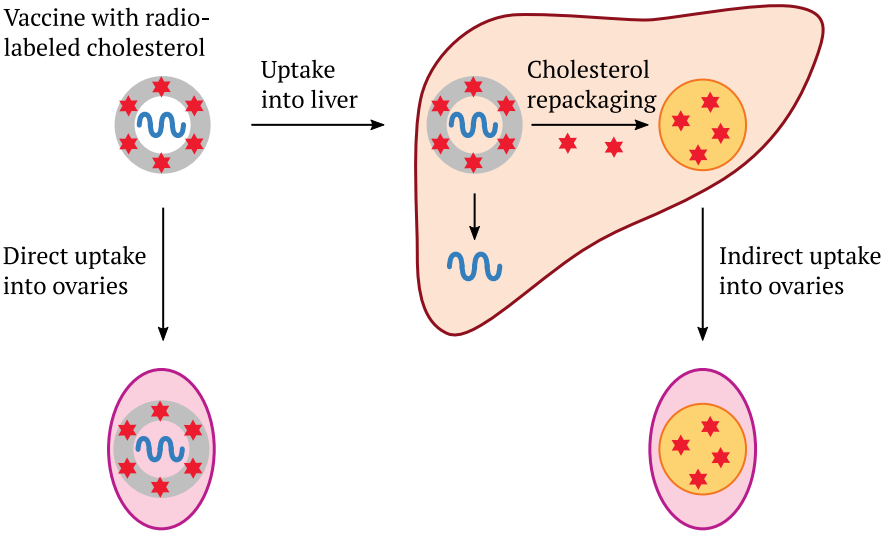
While the macrophages are likely responsible for most of the uptake in the spleen, this may not be the case in the liver. Here, the vaccine likely ends up mostly in the organ-specific epithelial cells, which are very rich in lipoprotein receptors. Uptake into the ovaries and into the adrenal glands is most likely also mediated by lipoprotein receptors. Both organs take up lipoproteins to obtain cholesterol, which they use as a precursor for producing steroid hormones—corticosteroids in the adrenal glands, and female sexual hormones (estrogens and progestins) in the ovaries.

The testes, too, produce sexual hormones (in particular testosterone) from cholesterol, but here the accumulation of vaccine lipid is remarkably much lower. The scientific literature does not offer a full, straightforward explanation for the restricted uptake into the testes, but it may be related to the so-called blood-testes-barrier. In most other organs examined the levels were similarly low as in the testes. We note, however, that at least the blood vessels will be affected in every organ and in every tissue.

2.2 Direct vs. indirect transport of radiolabel to the ovaries

It is noteworthy that the level of radioactivity in the liver rises very fast within the first eight hours but then stagnates, whereas in the ovaries and the adrenal glands the rise continues even two full days after the injection. This suggests that the radioactivity may be redistributed from the liver to these glands. In this context, we must remember that the LNP component which carried the label was cholesterol. The labeled cholesterol would behave just like endogenous (unlabeled)

cholesterol, and after uptake into the liver we would expect it to be recycled and redistributed to other organs. Cholesterol redistributed from the liver would likely be unaccompanied by the mRNA. Therefore, the question whether the cholesterol found in the ovaries is acquired in this indirect manner or through direct uptake of the vaccine is of considerable importance.



In addition to cholesterol, the vaccine LNPs contain another naturally occuring lipid (distearoyl-phosphatidylcholine) and two non-natural ones (see below). Thus, we must ask to what extent these other lipids would undergo redistribution from the liver and then also accumulate e.g. in the ovaries.

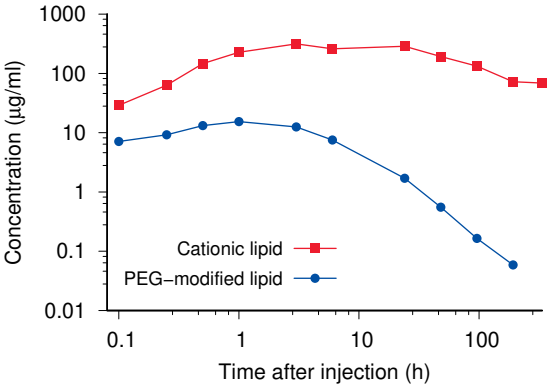
Finally, it must also be noted that the distribution of the vaccine might be affected by the protein encoded by its mRNA component. If instead of the presumably inert luciferase enzyme the spike protein had been expressed, this might have affected vascular integrity, particularly also at the blood brain barrier. This might translate into increased uptake into other organs, including the central nervous system.

Each of the posed questions could readily have been answered using experiments similar to those reported by Pfizer—in particular, each of the relevant lipids should have been radioactively labeled in turn, and the proper mRNA encoding the actual spike protein should have been used instead of the one encoding luciferase. It should go without saying that the FDA, the EMA and other regulators should never have authorized the use of the vaccine without mandating and reviewing thorough studies of this kind.

2.3 Very slow elimination of the cationic lipid ALC-0315 from rat liver

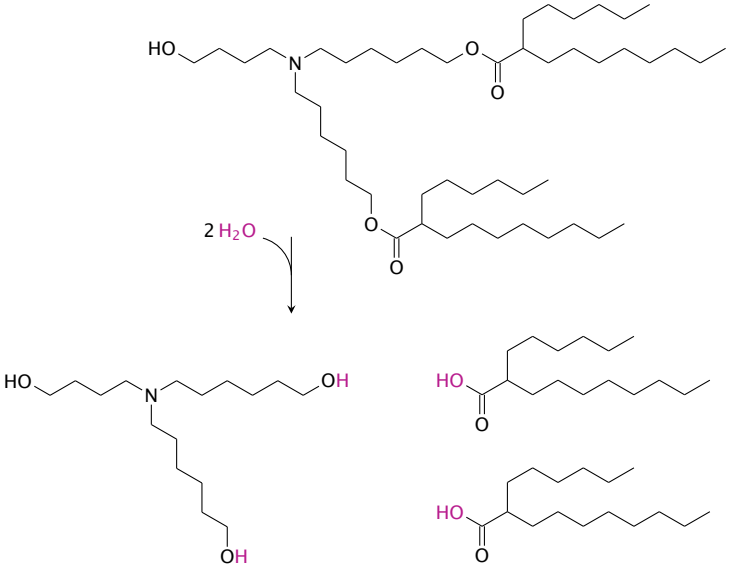
Of the two non-natural lipids contained in the vaccine LNPs, one (ALC-0315) is weakly basic, whereas the other (ALC-0159) carries a polyethyleneglycol (PEG) moiety. As just discussed, no comprehensive distribution studies on these lipids were carried out. However, Pfizer did report the change over time of their concentrations within the liver. The level of the PEG-modified lipid dropped slowly but regularly

with time. The other one, however—the cationic lipid ALC-0315—remained at very high levels at two weeks (336 hours) after the injection. Even after 6 weeks some of the compound was still detected in liver. As discussed in the preceding section, we cannot rule out that these synthetic lipids, too, are redistributed from the liver to other organs, where they might then be stored for even longer periods of time.



You may have heard that some pesticides such as DDT can persist in the human body for months and even years. This typically occurs with compounds which are very *lipophilic*, meaning that they partition into fat droplets within fat tissue and other organs. As long as the fat within these droplets is not utilized, the chemicals dissolved within them will be safe from metabolic turnover and degradation. The cationic lipid ALC-0315 is likely able to accumulate in the same manner. If so, we can expect persistence for even longer periods of time than evident from this graph in tissues that have lower metabolic activity than the liver.

2.4 Slow degradation is built into the structure of ALC-0315



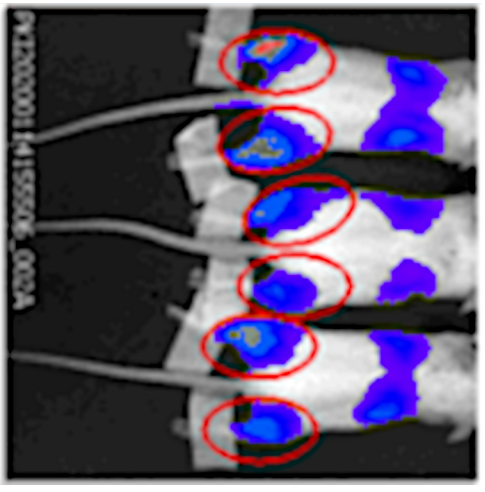
This topic is rather technical, and it is not necessary for the big picture. If you can't make out what this diagram is showing, feel free to skip it.

The structure at the top shows the intact cationic lipid referred to as ALC-0315. Hydrolysis of the two ester (C(=O)O) bonds produces the three fragments at the bottom; according to Pfizer's document, this is the initial step in the degradation and elimination pathway of this lipid. The following features suggest that inside the body this step will occur rather slowly:

1. The entire molecule contains no permanent charge and only one ionizable atom (the nitrogen, N), which is linked to three alkyl chains. Aside from the one polar hydroxy (OH) group, the entire remainder of the molecule is hydrophobic. This means that the molecule will partition very strongly not only into lipid bilayers (membranes) but also into lipid droplets, where it will be effectively hidden from any degradative enzymes.
2. When this molecule is part of a lipid bilayer, as is the case within the vaccine LNPs, the two ester bonds will still be buried deep within the hydrophobic portion of that bilayer, which will protect them from hydrolytic cleavage.
3. Hydrolysis of the ester bonds will to some degree be sterically hindered by the the adjacent branches in the fatty acyl residues.

With the possible exception of the lack of a permanent charge, none of these features is essential for the desired function of the molecule, namely to release the mRNA from the vaccine particles after the latter have been taken up into our body cells. There are many ways in which this molecule could have been modified for faster degradation in vivo. It is therefore noteworthy that this was not done—the vaccine was deliberately formulated with a compound that is degraded and eliminated from the body very slowly. Given that this lipid will most likely stay in our tissues for months, we must expect *cumulative toxicity* with repeated vaccinations.

2.5 Strong expression of luciferase in the rat liver and spleen



This picture is taken from the Pfizer study. As far as I can tell, it shows three skinned rat bodies. The time point of the measurement is 6 hours after the injection. The red ovals indicate the injection sites in the hind legs, and the various colors (mostly blue) within them indicate the luminescence produced by the local expression of luciferase. This luminescence indicates that the vaccine entered cells near the injection sites and successfully delivered its mRNA to the ribosomes within the cell.

The separate blue and purple areas to the right are over the liver and the spleen. Thus, the pronounced accumulation of lipid in these organs correlates with strong expression of the delivered luciferase mRNA also.

2.6 Does the correlation between lipid uptake and mRNA expression apply to other organs, too?

- Only cholesterol was traced, but distribution of mRNA was not
- Luciferase or spike protein expression could have been tested with other organs, but no such results were reported
- Distribution of mRNA could easily have been traced directly

In Section 2.2, we noted that radiolabeled cholesterol might reach organs other than the liver, in particular the ovaries, either through uptake of the vaccine particles themselves by these organs, or indirectly after initial uptake into the liver, where it would be repackaged into newly synthesized lipoprotein particles. In the former case, the radioactivity would be accompanied by the mRNA, whereas in the latter it likely would not be. It would therefore have been important to study the expression of the mRNA in these other organs also.

Rat ovaries are small, and therefore luminescence measurements on this organ might not be very sensitive; however, in that case, such measurements could have been performed on a larger animal species. Expression of the spike protein itself could have been measured using labeled antibodies. At the very least, if expression analysis was deemed too cumbersome, it would have been easy enough to detect the uptake of the mRNA itself into different tissues, for example by labeling it with radioactive iodine [4]. Such measurements would have been even more accurate and straightforward than those which were actually carried out for the lipids.

Since such experiments would not have been particularly difficult, I suspect that Pfizer did in fact perform them, but decided not to report the results. Be that as it may, however—we do know that most of the lipid will remain bound to the mRNA until after both have been taken up into cells. In the absence of proof positive to the opposite, we must therefore assume that a close correlation exists between lipid uptake, mRNA uptake, and mRNA expression. This raises obvious concerns for the health and integrity of the ovaries.

3 What do Pfizer's animal data presage for biological effects in humans?

- Rapid appearance of spike protein in the circulation

- Toxicity to organs with observed high rates of uptake
- Toxicity to organs with *expected* high rates of uptake, in particular placenta and lactating breast glands
- Penetration of some organs might be higher with the real vaccine than with this luciferase model

The rapid entry of the model vaccine into the circulation means that we must expect the spike protein to be expressed within the circulation, particularly by endothelial cells. We have seen before that this will lead to activation of blood clotting through direct activation of platelets and also, probably more importantly, through immune attack on the endothelial cells.

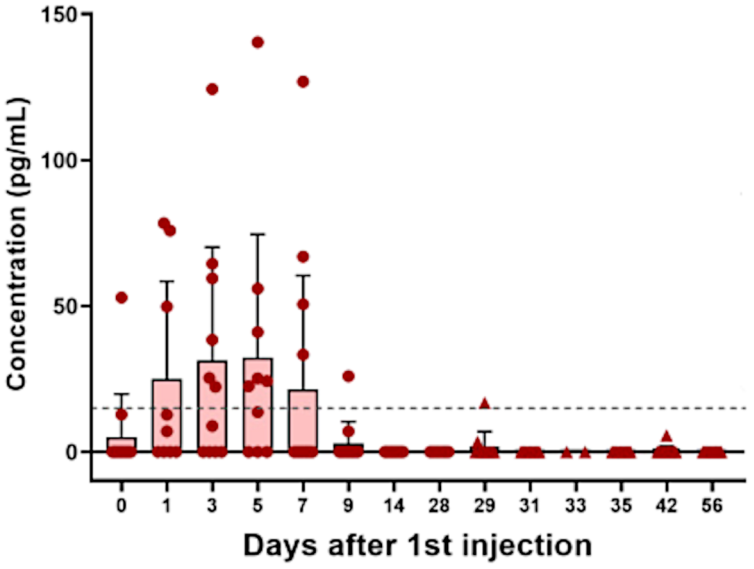
We must furthermore expect damage to organs that take up high amounts of the vaccine. The EMA assessment report on the Pfizer vaccine [5] does in fact mention such organ damage (see Section 3.4). The toxicity will likely pertain to some organs that were not examined in Pfizer's study. This includes in particular the placenta, which like the ovaries produces large amounts of progestin hormones from cholesterol, likewise acquired from circulating lipoproteins, and the lactating mammary glands, which acquire fat and cholesterol contained in lipoproteins for secretion into the breast milk.

The distribution studies discussed here did provide some useful and relevant information; however, as already noted in Section 2.2, the expression of the spike protein instead of the presumably inert luciferase enzyme might affect the distribution of the vaccine due to its interference with vascular integrity, including at the blood brain barrier. The actual COVID vaccine might therefore achieve greater entry into the brain than the luciferase model vaccine. The FDA, the EMA and other regulators should have insisted that such experiments be carried out and documented.

3.1 Expression of spike protein shortly after injection of an mRNA vaccine into humans

The early entry of the vaccine into the circulation observed in animals leads us to expect the same in humans. In keeping with this, spike protein becomes detectable in the blood plasma of human vaccinees even on the day of the injection (day 0) and peaks several days later [6]. Note that this assay measured only the S1 fragment which was cleaved from the cell surface and released, not the intact spike protein that remained on the cells (see Section 1.1).

The triangles on day 29 and later in the figure indicate the levels of free S1 fragment after the second injection. The very low levels most likely do not reflect a failure of the injected mRNA to be expressed, but rather result from the immune response triggered by the first injection. Circulating antibodies will bind to the spike protein and interfere with its measurement. The resulting spike-antibody complexes may be cleared from the bloodstream by phagocytes, but they may also contribute to inflammation. The same antibodies would also bind to the spike protein that remains on the cells. Once bound, they can set off the *complement system*, a cascade of plasma proteins that ultimately kills cells by punching holes into them [7].



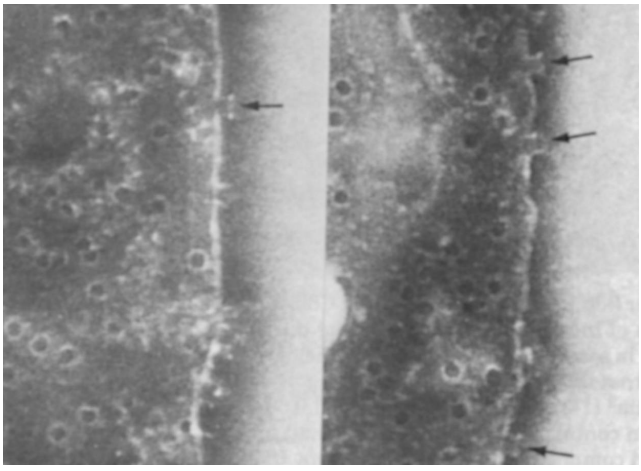
Together with rising antibodies, the first injection will also induce T-killer cells directed against the spike-producing cells (see Section 1.1). The more rapid and intense cytotoxic action of these T-cells may destroy the cells which took up the vaccine before they had much time to produce spike protein. Whatever the relative contributions of antibodies/complement and of cytotoxic T-cells to the suppression of free spike protein levels may be, it is clear that this finding indicates greater harm to the blood vessels after the second injection than after the first.

We should mention that the above data were obtained from a fairly small sample—13 persons overall, out of whom 11 exhibited detectable free S1 fragment. Quite possibly, even higher levels would have been observed among a larger group of test persons. Altogether, the findings in this study substantiate the hypothetical mechanism of vaccine-induced blood clotting that was stated clearly and early on by the Doctors for Covid Ethics [8], and which has since been fully borne out by experience [9].

3.2 Complement pores on the surfaces of red blood cells

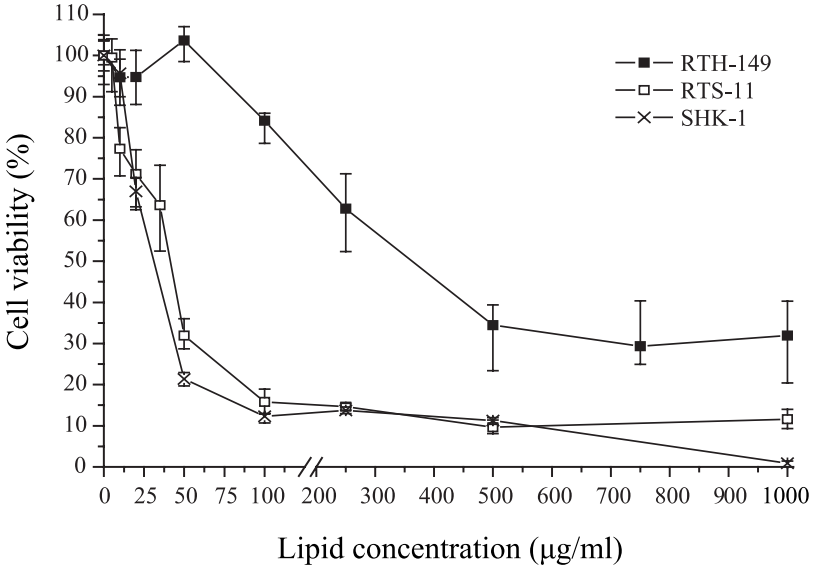
We just saw that in particular the second injection will likely cause the activation of the complement system on endothelial cells. This picture, which is taken from a seminal paper on the action mode of the complement system [7], illustrates that the complement system is perfectly capable of "shooting up the joint"—of utterly destroying a cell.

In the depicted experiment, antibodies against sheep red blood cells were allowed to bind to such cells in the presence of human serum, which provided the complement proteins [10]. As you can see, the cells are riddled with holes. An individual pore consists of multiple complement protein molecules; it protrudes from the membrane (see arrows) and has a diameter of approximately 10 nanometers. The pores will break down the barrier function of the cell membrane, and the cell will die.



Similar effects must be expected with endothelial cells downstream of spike protein expression and antibody binding. The damage to the capillaries will promote vascular leakage as well as blood clotting.

3.3 Cationic lipids are cytotoxic



This graph is taken from a study [11] that is not related to the Pfizer vaccine; it is included here only as an illustration of cationic lipid toxicity in general. It shows the dose-dependent effect of the cationic lipid in question (stearylamine) on the viability of three different cell lines. Among these, the two macrophage-like lines RTS-11 and SHK-1 are more sensitive to the cytotoxic effect than the liver-derived cell line RTH-149.

While the various cationic lipids that have been used for DNA or mRNA delivery differ in cytotoxicity, they all are toxic to some degree; and as this figure illustrates, various cell types differ in susceptibility. The high susceptibility of macrophages is due to their built-in capability to produce reactive oxygen species (ROS) such

as hydrogen peroxide and superoxide. When this pathway is triggered by cationic lipids, the ROS produced may kill the cells outright—as observed in the depicted experiment. A lower level of activation may cause the macrophages to "misbehave," which may lead to inflammation, autoimmune disease, and potentially cancer.

It is interesting to note that the above-mentioned evidence of liver and muscle toxicity in the EMA report was obtained with the model mRNA encoding the presumably non-toxic luciferase enzyme. Therefore, this observed toxicity does not involve the spike protein. Luciferase, unlike spike protein, is not transported to the cell surface; and moreover the animals will have had no pre-existing immunity to luciferase that could have set off a rapid, intense immune response. We thus infer that the reported cell damage is due to chemical toxicity, mediated most likely by the cationic lipid components of the LNPs. Accordingly, future vaccines that use the same delivery technology must also be expected to share this toxicity, regardless of whether they be directed against the spike protein, another SARS-CoV-2 antigen, or a different antigen or disease altogether.

3.4 Toxicity in tissues and organs

- Muscle fiber degeneration and scarring
- Subcutaneous inflammation
- Liver cell vacuolization and degeneration
- Inflammation and function damage to nerves and joints

These findings from rat experiments are listed in the EMA report [5]. They, too, were obtained using the model vaccine which coded for luciferase rather than the actual SARS-CoV-2 spike protein, which means that the toxicity is most likely due to the cationic lipids in the LNPs. It must be noted that none of these toxic effects observed in animals were monitored in the so-called clinical trials. They do, however, correspond to adverse effects observed in vaccinees since the onset of mass vaccinations.

3.5 Animal data on reproductive toxicity

- Very limited data collected in only one animal species (rats)
- Loss of early embryos before implantation in the uterus >2 times more common in vaccine group than in controls
- Malformations more common in vaccine group than in controls

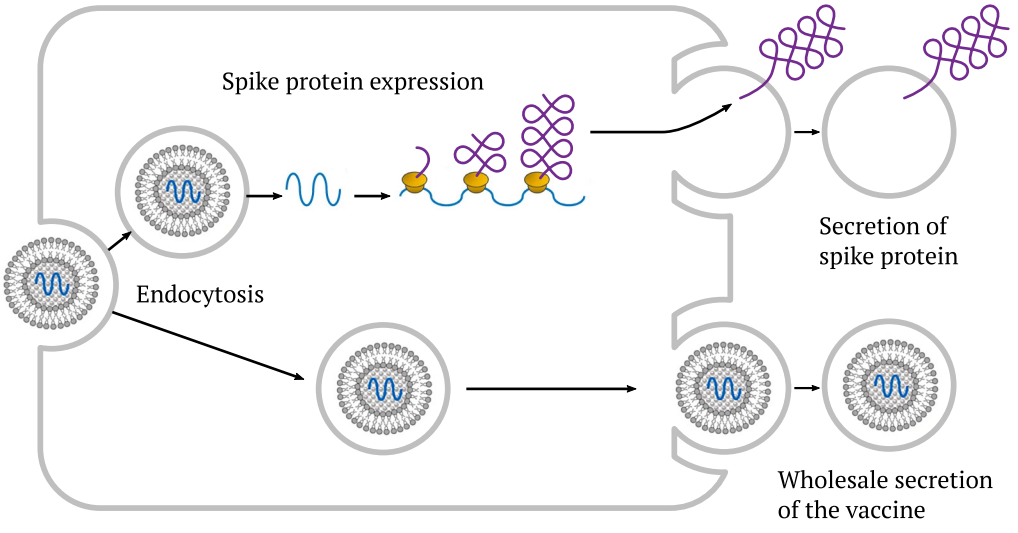
Pfizer tested its vaccine for reproductive toxicity on only one species (rats) and on only small numbers of animals (21 litters). A greater than twofold increase in pre-implantation loss of embryos was noted, with a rate of 9.77% in the vaccine group, compared to 4.09% in the control group. The EMA report merely states that the higher value was "within historical control data range" [5, p. 50]. EMA should of course have obligated Pfizer to state unambiguously whether or not the observed

difference was statistically significant; and if it was not, to increase sample sizes so as to ensure the required statistical power.

The same criticism applies to the reported observations of "very low incidence of gastroschisis, mouth/jaw malformations, right sided aortic arch, and cervical vertebrae abnormalities." Overall, Pfizer's studies are inadequately described and apparently were also inadequately carried out.

The observed pre-implantation loss indicates toxicity at a very early stage of development, either to the embryo or the nascent placenta. It might be caused by a high level of spike protein expression, but also by toxic lipids; and it might occur already within the ovaries, but also affect the fertilized egg or subsequent developmental stages within the Fallopian tubes or the uterus. This also applies to malformations, although these would more likely be caused by damage later on in embryonic development, suggesting transfer of toxicity across the placenta.

3.6 Two possible pathways for vaccine toxicity to breastfed infants



Uptake of the vaccine by mammary gland cells opens two possible pathways of toxicity to the breastfed child: firstly, the expression of spike protein and its secretion into the breast milk, and secondly, the wholesale transfer of the vaccine into the milk.

The mammary glands are *apocrine*, which means that they pinch off and release fragments of their own cytoplasm into the milk; thus, anything that has reached the cytoplasm might also reach the breast milk. In this connection, we note that both the VAERS database and the EU drug adverse events registry (EudraVigilance) report fatalities in breastfed newborns shortly after vaccination of their mothers. At least in some cases, the clinical picture included diffuse bleeding, which has also been observed in vaccinated as well as in SARS-CoV-2-infected adults. Of course, these cases should have triggered a careful search for vaccine components in breast milk, and a targeted study of breast-fed infants of vaccinated mothers. A recent PCR-based study found no mRNA in the breast milk, but the methodology of that

study is questionable [12]. Studies on the presence of spike protein in the milk seem to be lacking entirely.

4 Summary

Pfizer's animal data clearly presaged the following risks and dangers:

- blood clotting shortly after vaccination, potentially leading to heart attacks, stroke, and venous thrombosis
- grave harm to female fertility
- grave harm to breastfed infants
- cumulative toxicity after multiple injections

With the exception of female fertility, which can simply not be evaluated within the short period of time for which the vaccines have been in use, all of the above risks have been substantiated since the vaccines have been rolled out—all are manifest in the reports to the various adverse event registries [9]. Those registries also contain a very considerable number of reports on abortions and stillbirths shortly after vaccination, which should have prompted urgent investigation.

We must emphasize again that each of these risks could readily be inferred from the cited limited preclinical data, but were not followed up with appropriate in-depth investigations. In particular, the clinical trials did not monitor any laboratory parameters that could have provided information on these risks, such as those related to blood coagulation (e.g. D-dimers/thrombocytes), muscle cell damage (e.g. troponin/creatine kinase), or liver damage (e.g. γ-glutamyltransferase). That the various regulatory agencies granted emergency use authorization based on such incomplete and insufficient data amounts to nothing less than gross negligence.

Of particularly grave concern is the very slow elimination of the toxic cationic lipids. In persons repeatedly injected with mRNA vaccines containing these lipids—be they directed against COVID, or any other pathogen or disease—this would result in cumulative toxicity. There is a real possibility that cationic lipids will accumulate in the ovaries. The implied grave risk to female fertility demands the most urgent attention of the public and of the health authorities.

Since the so-called clinical trials were carried out with such negligence, the real trials are occurring only now—on a massive scale, and with devastating results. This vaccine, and others, are often called "experimental." Calling off this failed experiment is long overdue. Continuing or even mandating the use of this poisonous vaccine, and the apparently imminent issuance of full approval for it are crimes against humanity.

References

[1] Anonymous: *SARS-CoV-2 mRNA Vaccine (BNT162, PF-07302048) 2.6.4 [Summary statement of the pharmacokinetic study] (Japanese)*. 2020. URL: https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf.

[2] Anonymous: *SARS-CoV-2 mRNA Vaccine (BNT162, PF-07302048) 2.6.4 Summary statement of the pharmacokinetic study [English translation]*. 2020. URL: https://archive.org/details/pfizer-confidential-translated.

[3] V. Francia et al.: The Biomolecular Corona of Lipid Nanoparticles for Gene Therapy. *Bioconjug. Chem.* 31 (2020), 2046–2059. PMID: 32786370.

[4] M. A. Piatyszek et al.: Iodo-Gen-mediated radioiodination of nucleic acids. *Anal. Biochem.* 172 (1988), 356–9. PMID: 3189783.

[5] Anonymous: *Assessment report/Comirnaty*. 2021. URL: https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf.

[6] A. F. Ogata et al.: Circulating SARS-CoV-2 Vaccine Antigen Detected in the Plasma of mRNA-1273 Vaccine Recipients. *Clin. Infect. Dis.* (2021). PMID: 34015087.

[7] S. Bhakdi and J. Tranum-Jensen: Molecular nature of the complement lesion. *Proc. Natl. Acad. Sci. U. S. A.* 75 (1978), 5655–5659. PMID: 281714.

[8] S. Bhakdi et al.: *Urgent Open Letter from Doctors and Scientists to the European Medicines Agency regarding COVID-19 Vaccine Safety Concerns*. 2021. URL: https://tinyurl.com/d4ce-letter.

[9] L. Johnson: *Official Vaccine Injury and Fatality Data: EU, UK and US*. 2021. URL: https://doctors4covidethics.org/official-eu-adverse-event-data-eu-uk-us/.

[10] J. Tranum-Jensen et al.: Complement lysis: the ultrastructure and orientation of the C5b-9 complex on target sheep erythrocyte membranes. *Scandinavian journal of immunology* 7 (1978), 45–6. PMID: 635472.

[11] K. Romøren et al.: Transfection efficiency and cytotoxicity of cationic liposomes in salmonid cell lines of hepatocyte and macrophage origin. *Biochim. Biophys. Acta* 1663 (2004), 127–34. PMID: 15157615.

[12] Y. Golan et al.: Evaluation of Messenger RNA From COVID-19 BTN162b2 and mRNA-1273 Vaccines in Human Milk. *JAMA pediatrics* (2021). PMID: 34228115.