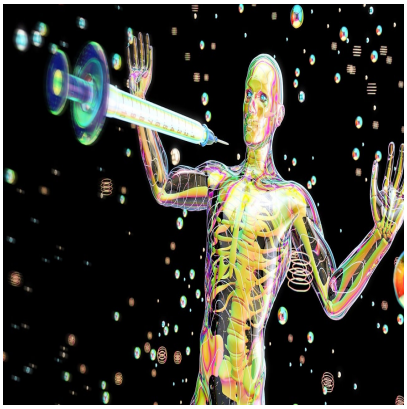

The Modified RNA Vaccination Platform is Becoming the Norm for Vaccinations, It Seems…

Description

…and this is what needs to be avoided: the approval of Moderna's mResvia (mRNA1345) proves it

On 15 August 2024, the US Advisory Committee on Immunization Practices (ACIP), issued a recommendation that older people aged 60 and over should receive a dose of a respiratory syncytial virus vaccine. The Centers for Disease Control, the public health authority, recently published this in its weekly report [1]. A new product appears prominently there, the modified RNA prevention, mRNA1345 from Moderna, which is sold under the trade name *mResvia*.

This is a new gene therapy prevention therapy, referred to as a 'vaccine'. The corresponding approval study was published in 2023 [2]. I took a closer look at this because I was once again interested in the risk-benefit ratio.

It is important to know that respiratory syncytial viruses (RSVs) are common viruses that are found in every kindergarten, every school class, and every nursing home. Anyone who comes into contact with them and is susceptible will get a cold, cough, hoarseness, maybe even a fever: especially in older people, an infection can develop that takes a more severe course. Probably similar to a corona infection. Basically harmless. Exceptions not ruled out.

Approval study of mRNA1345 *mResvia* by Moderna

The approval study by Wilson, a Moderna employee, examined the effectiveness of this new 'vaccine' in old people over 60 years of age. Because, so the argument, these are particularly at risk. The incidence estimates in older people, i.e. how many people are affected by it at all, are, according to studies cited by Wilson, 3-10% of older people in industrialised countries. 33,000 deaths in hospitals in Western countries are attributed to thisvirus. If we assume a population of about 450 million for the EU and 345 million for the USA, then we aretalking about a mortality rate of 0.004% of the total population of these countries. Assuming that about a third ofthe population of industrialised countries is over 60, we are talking about an incidence of 0.14 per thousand ofRSV-associated deaths. Thus, we are not dealing with a dramatic issue.

It seems, now, the abolition of death is to begin with vaccinating the elderly against RSV. Notably, the recruitment for this study ran from November 2021 to October 2022, a year after the major Covid-19 'vaccination campaign' was carried out, or at the same time as the Covid-19 booster campaign. As can be seen from the supplement to this publication, a simultaneous or previous Covid vaccination (at least one month beforehand) was a criterion for exclusion. However, this means that, above all, really healthy people were recruited here, 'spry old-timers', as they are often called, precisely those who had either refused the Covid-19 'vaccination' or, more likely, had already had it more than a month before. Nothing is known about this. But it shows that Moderna has developed and tested at least one other vaccine in parallel with the Covid-19 modRNA 'vaccine'. We also know that a flu modRNA preventive vaccine is in the approval process.

This suggests that the modified RNA platform will most likely become the basis for many more vaccines. That's convenient. Because once you have the production pipeline, you can use it for all sorts of other things. And it supports my argument – see my blog on transhumanism – that the commodification of the human body, i.e. the economic exploitation of health, is high on the agenda.

So it is useful to have a close look at this RSV prevention study. As usual with such publications in the New England Journal of Medicine, this work is solidly designed and reported and, at first glance, completely positive. Real placebo was used as a control, saline solution. The study was blinded. The data was apparently collected by contract research organisations, i.e. companies specialising in such work. The authors are also very outspoken: the first author is an employee of Moderna. The company is not only a sponsor in the sense of pharmaceutical law, i.e. it initiated the study and covered all costs. It also handled the design planning, data collection, evaluation and publication. The text was written by medical writers. Recruitment took place in 22 countries and included 35,541 people.

As I have explained before, the size of a study is a direct function of the expected effect – the larger the effect, the smaller the study. The larger the study, the smaller the effect. This is because including patients or individuals in studies is expensive, and also because ethics committees always want to see a statistical power analysis. I've discussed this in my methodology blogs. In short, it means that you have to be aware of the necessary size of a study. The number of subjects in a study depends primarily on the expected effect. If you know or estimate this, you can calculate how many people you need to include. Ethics committees generally want to see that a suspected effect can be demonstrated with a relatively high probability (statistically: power) and that an appropriate number of patients, but no more than necessary, are included.

The numbers are always large in vaccination and prevention studies. This is because the events that are to be prevented do not normally occur in every study participant. Lipid-lowering studies often have high five-digit patient numbers because the events they are designed to prevent, such as mortality, can only rarely be prevented.

This was also the case here. The criterion of this study was to prevent the new occurrence or worsening of a respiratory disease with either 2 or 3 symptoms. A hard criterion, such as the prevention of hospitalisation or death, was not even considered. That would probably have required 10 or 100 times as many study participants.

Even so, the incidence of the disease to be prevented, namely respiratory disease with 2 or 3 symptoms, was not exactly breathtakingly high. That's why so many people had to be 'vaccinated' and examined.

Relative and absolute risk reduction

I will present the most important data below. And unlike the publication, I will not state the relative effectiveness, but the absolute risk reduction. This is calculated based on the number of cases, calculated based on the total number of study participants in the control group minus the number of cases in the treatment group, standardised based on the number of participants in this group. The difference should be clear. If, as in this case, 9 study participants in the treatment group fell ill and 55 did so in the control group, the result is a *relative* risk reduction or *vaccine effectiveness* of 84% (because 9/55 = 0.16, and 1 – 0.16 = 0.84).

That sounds impressive. But you always have to consider: 9 or 55 out of how many people? If you include the total number, you get the absolute risk reduction (ARR). And that is less impressive. If you calculate 1/ARR, you get the number needed to vaccinate (NNV), the number of people you have to treat to prevent one case (as defined here). I present this in the table below.

	Treatment group n = 17,572	Placebo* n = 17,516	ARR#	NNV§
Disease with 2 symptoms	9	55	0.0026	380.5
Disease with 2 symptoms	3	17	0.0008	1,250

Table 1 – Effects of the study of mRNA 1345, *mResvia* from Moderna, from [2]

*Saline solution; # = absolute risk reduction; § = number needed to vaccinate

As can be seen from Table 1, RSV infections are rare, even if left untreated, calculated on the large number of participants: 3 per thousand develop an illness with 2 symptoms if left untreated, 0.9 per thousand develop a more severe illness with 3 symptoms if left untreated.

Now, relative effectiveness rates of preventive intervention of 82% or 84% sound very impressive. But when extrapolated to the total number of patients treated, the absolute risk reduction rates are very modest. And conversely, the number needed to vaccinate is relatively high: 380 people have to be vaccinated to prevent a mild case of RSV respiratory disease with 2 symptoms, and 1,250 to prevent a more severe case with 3 symptoms. Hospitalisations and deaths were not recorded. They would not have occurred with this number of participants, they are that rare.

Doesn't matter, some may think. The main thing is to prevent a few cases of illness. That would be true if the intervention had no side effects. But it does. No intervention is without side effects.

Side effects

But with preventive interventions such as vaccinations and others that are supposed to benefit everyone, all those who are treated without themselves deriving any benefit from it are exposed to the risk potential. This is typically hidden in the appendix of such publications. I had a look at it and extracted just a few interesting details in the

following Table 2.

Table 2 – Some side effects and their frequencies from [2], supplement

Nebenwirkungen	Number (%)	Lasting more than 7 days
All systemic (e.g. headache, exhaustion)	8.432 (47.7%)	1.034 (5.9%)
Headache	4.764 (27%)	315 (1.8%)
Exhaustion	5.470 (31%)	606 (2.3%)
Joint pain	3.867 (21.9%)	311 (2.9%)
Severe side effects that led to medical treatment or were life-threatening	1.104 (6.2%)	—
Spontaneous reports of adverse events associated with the intervention	1.033 (5.8%)	—

These are only a selection of the adverse events. All adverse events except for those in the last row were actively queried. This means that the study participants either received a questionnaire with categories or the study doctors actively asked about them. The spontaneous ones are those that are reported without being directly queried. It should also be kept in mind that such reports are typically also made in the placebo group. Perhaps because the background noise is high, or the questionnaires have a suggestive effect, or because there are real correlation effects, as we have explained elsewhere [3].

That's why it's difficult to evaluate such side effect data properly. But I think that if you want to know whether a small effect is worth accepting potential side effects, then such considerations are still helpful.

Because we see: the risk of such a disease is low because the incidence in the target group is in the per mille range or below. Therefore, you have to treat several hundred to a thousand people to prevent a single case. But all the 379 or 1249 people who are treated unnecessarily, so to speak – because you can never know who will develop the disease – all suffer the risk of a side effect. And as we can see from the table above, this is in the percentage range. And even if we subtract these numbers from those of the placebo group, the risk potential remains higher than without vaccination.

Risk-benefit analysis

The 1,033 cases of spontaneously reported side effects in the treatment group that are associated with the intervention are offset by 803 in the placebo group. If we conservatively assume that 803 represent background noise, then at least 230 people in the treatment group experience side effects that are associated with the treatment, which certainly do not represent background noise.

In other words: 230 people have some problems due to the intervention that they would not have had without the intervention. On the other hand, the disease is prevented in a total of 60 people (the two columns added up in the placebo group in Table 1 minus the two in the treatment group).

To put it another way: the risk-benefit profile is unconvincing, to put it kindly.

And that's not counting the obvious weaknesses, such as the fact that only a 4-week observation of side effects is available and thus possible long-term problems are not covered. The long-term effects of the intervention over 12 months are quite convincing in the figures of the publication, but they do not change the fact that the incidence of

the disease is very low overall and the necessity of an intervention is therefore questionable.

One can, if one must, ascribe a positive effect to the intervention for older people. But the fact that the necessity of a 12-month booster 'vaccination' has already been published here [4] supports my argument: we are facing a commodification of the human body. It is becoming the new commodity. After all, a sensible immunisation, e.g. by undergoing an illness or using a live vaccine, usually lasts a long time, often a lifetime, and certainly many years to decades.

If, as some people would like, these and other vaccinations are given to children on modRNA platforms, then everyone will have to constantly run to the vaccination centre. Or we move on to the next step: self-replicating vaccines. Such a self-replicating modRNA vaccine was recently approved in Japan. Yes, you read that right: this modRNA never stops; it replicates itself over and over again. Boosters are no longer necessary. Nor is freedom of choice.

The problem of mod RNA interventions in general

What we are seeing here is the beginning of a dangerous trend, namely to convert all normal vaccinations to the modRNA platform. And this must be prevented. Because: these 'vaccinations' are precisely not harmless. With the Covid 'vaccinations', it is gradually becoming apparent how many side effects they have.

Soon the cancer statistics will show that cancer deaths have increased rapidly. Many doctors I have spoken to report an increase in 'turbo cancer'. This is a cancer that develops faster than has often been seen before and is therefore practically untreatable. This is probably because modRNA has to be encapsulated in cationic, i.e. positively charged and ionisable, lipid particles in order for it to remain in the body long enough and reach its target, the cell. These lipid particles are therefore problematic in themselves. This is because cell membranes normally consist of neutral and negatively charged lipids. These negative charges occur mainly on the inside of the cell. Positively charged lipids as the outer side of the membrane do not occur in our physiology, except in cancer cells. Furthermore, the immune system has to be suppressed quite severely for a few days [5] so that it does not immediately start counter-reactions. And in this window of opportunity, a cancer can develop that could otherwise be kept in check by our immune system. It is also possible that the DNA plasmids that Dr. König detected in the Covid modRNA 'vaccines' play a role [6]. They come from the production process and are difficult to remove. They are still present in traces even in highly purified products. And nobody knows whether they could be introduced into the genome.

Even if a new modRNA prevention substance does not produce any spike proteins, the modRNA platform always remains problematic because it inherently, in principle and irreversibly, represents an attack on our natural immunity and a violation of our cell integrity. These substances produce a very specific immunity with the help of IgG antibodies. But they do this by temporarily suppressing natural, non-specific immunity and ignoring cell-mediated immunity through IgA antibodies (which can hardly be influenced by any kind of vaccination).

Prevent the modRNA platform and change the legal situation

We must therefore prevent this modRNA platform from becoming the general standard. By pointing out how problematic the principle is and that it did not work during the Corona pandemic either [7, 8].

In any case, the marketing of unsafe vaccines that have a high rate of side effects can be prevented. There is a simple political solution to this.

The legal situation must be changed. Because at the moment, the state is liable for vaccine damage. Therefore,

the state has no interest in them being recognised. Because our judiciary is not independent – public prosecutors are bound by instructions and judges are promoted by the state minister of justice based on their performance – this will not change quickly. However, if, as was previously the case, the side effects of vaccines are treated in the same way as the side effects of drugs, for which the manufacturers are liable, then the circus will be over quickly. Because then the companies have a vested interest in producing safe products and also ensuring that they are safe in the long term so that they are not held liable.

Therefore, my appeal to politicians and legislators is: change the law so that all vaccines are at least as safe as medicinal drugs! Their profile is not breathtaking either. If Peter Gøtzsche is to be believed, taking medication is the third most common cause of death in Western countries [9, 10]. However, vaccines and preventive interventions that are administered to large groups should be at least as safe as the shakiest drug candidates. And modRNA platforms should no longer be approved at all.

Sources and literature

1. Britton A, Roper LE, Kotton CN, Hutton DW, Fleming-Dutra KE, Godfrey M, et al. Use of Respiratory Syncytial Virus Vaccines in Adults Aged ?60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices – United States, 2024. MMWR Morbidity and mortality weekly report. 2024;73(32):696-702. Epub 2024/08/15. doi: https://doi.org/10.15585/mmwr.mm7332e1. PubMed PMID: 39146277.
2. Wilson E, Goswami J, Baqui Abdullah H, Doreski Pablo A, Perez-Marc G, Zaman K, et al. Efficacy and Safety of an mRNA-Based RSV PreF Vaccine in Older Adults. New England Journal of Medicine. 2023;389(24):2233-44. doi: https://doi.org/10.1056/NEJMoa2307079.
3. Walach H, Sadaghiani C, Dehm C, Bierman DJ. The therapeutic effect of clinical trials: understanding placebo response rates in clinical trials – A secondary analysis. BMC Medical Research Methodology. 2005;5:26.
4. Shaw CA, Essink B, Harper C, Mithani R, Kapoor A, Dhar R, et al. Safety and Immunogenicity of an mRNA-Based RSV Vaccine Including a 12-Month Booster in a Phase 1 Clinical Trial in Healthy Older Adults. J Infect Dis. 2024. doi: https://doi.org/10.1093/infdis/jiae081.
5. Sahin U, Karikó K, Türeci Ö. mRNA-based therapeutics — developing a new class of drugs. Nature Reviews Drug Discovery. 2014;13(10):759-80. doi: https://doi.org/10.1038/nrd4278.
6. König B, Kirchner JO. Methodological considerations regarding the quantification of DNA impurities in the COVID-19 mRNA vaccine Comirnaty. Methods and Procotols. 2024;7(41). doi: https://doi.org/10.3390/mps7030041.
7. Klement RJ, Walach H. Commentary: raised c-troponin levels as a sign of myocardial injury after COVID-19 vaccination in healthy individuals are worrying. The Egyptian Heart Journal. 2024;76(1):16. doi: https://doi.org/10.1186/s43044-024-00441-1
8. Klement RJ, Walach H. SEIR models in the light of Critical Realism – a critique of exaggerated claims about the effectiveness of Covid 19 vaccinations. Futures. 2023:103119. doi: https://doi.org/10.1016/j.futures.2023.103119.
9. Gøtzsche PC. Deadly Psychiatry and Organised Denial. Copenhagen: People's Press; 2015.
10. Gøtzsche PC. Deadly Medicines and Organised Crime: How Big Pharma Has Corrupted Health Care. London: Radcliff; 2013.

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