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Will the mRNA flu vaccine come into being?

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At the end of November 2025, the *New England Journal of Medicine* published an article on a clinical trial of a messenger RNA vaccine against seasonal influenza. The article was written by researchers working for Pfizer, the company that developed the vaccine. Pfizer is keen to show that its vaccine is more effective than conventional vaccines. However, independent experts have pointed out major omissions and inconsistencies in the publication, which minimise or even call into question the trial's conclusions.

As early as 1990, the first work on messenger RNA (mRNA) vaccines focused on combating seasonal flu, but encountered technical difficulties inherent in the mRNA molecule when introduced into an organism[1]. Biotechnological innovations and nanotechnologies subsequently made it possible to overcome certain implementation difficulties and develop mRNA injections against Covid-19[2].

Pfizer has been working since September 2021 on the development of an mRNA vaccine against influenza[3]. The advantage of such a vaccine, as stated by the company, would be that it could be produced quickly to cope with the rapid mutations that affect influenza viruses. The article[4]

published in the *New England Journal of Medicine* (*NEJM*) concerns the phase 3 clinical trial, the last stage before a possible marketing authorisation application[5].

After presenting the "*vaccine*" that Pfizer is working on, we will look at the flaws in this phase 3 trial and the data discarded by Pfizer in the dedicated article. We will therefore question the validity of this trial. A critical eye is needed, as mRNA is a new industrial biotechnology production platform that is regularly cited as an example to be promoted in agriculture and medicine. In the latter field, the European Commission's proposal for a "*Biotech Regulation*" seeks precisely to open the doors wider to biotechnology in medicine[6]. However, the results we will discuss show that with this type of vaccine, we are moving closer to a form of medicine that generates additional risks rather than benefits.

A quadrivalent messenger RNA vaccine

For the development of seasonal influenza vaccines, regardless of how they are manufactured (messenger RNA or otherwise), the World Health Organisation (WHO) issues annual recommendations on the circulating strains to be taken into account for vaccine production[7]. The vaccine can be, for example, trivalent or quadrivalent, depending on the number of recommended virus strains. The mRNA vaccine in the Pfizer trial is quadrivalent, meaning that it is designed to combat four virus strains: two A strains (A/H3N2 and A/H1N1) and two B strains (B/Yamagata and B/Victoria)[8].

The mRNA in the Pfizer vaccine is a mixture of the four genetically modified viral mRNAs. Each of these injected mRNAs should enable the synthesis of a modified viral haemagglutinin (viral protein chosen as an antigen) specific to each of the four selected virus strains. The genetic modifications made to the mRNA molecules are similar to those made to the anti-Covid mRNA vaccine to optimise its action: stabilising it to evade the immune system. These mRNAs are encapsulated in lipid nanoparticles, as in the anti-Covid vaccine. However, this vaccine with four genetic mRNA constructs is, in fact, much more complex than the mRNA vaccine against Covid.

Omission or minimisation of data

The published article gives the results deemed positive by Pfizer concerning the action of its vaccine in 18-64 year olds, but does not include the results for people aged 65 and over, an age group that is nevertheless heavily affected by seasonal flu. However, this age group represented 60% of the participants in the overall Phase 3 trial involving all adults aged 18 and over, as shown on the ClinicalTrials.gov website[9].

Based on the complete data on ClinicalTrials.gov, some independent experts (epidemiologists, microbiologists, physicians, pharmacologists) have calculated that, compared to the conventional inactivated influenza vaccine[10], seniors experienced an 8% increase in serious adverse events, an 80% increase in non-serious adverse events, +129% acute renal injury, unspecified (16 vs. 7), +184% acute respiratory failure (17 vs. 6), and low but slightly higher all-cause mortality[11]. The complete data show a comprehensive picture of results, particularly for adverse effects in people aged 65 and over, which the *NEJM* article does not mention.

In France, this shortcoming is cautiously mentioned in the journal *Fréquence Médicale*[12], which notes in its article that "*the focus on healthy 18-64 year olds limits the scope of direct extension to children, people aged 65 and over, pregnant women and immunocompromised individuals*". It goes on to state that the prospects for this vaccine must include, among other things, "*dedicated trials in seniors*".

It should also be noted that, although the results for 18-64 year olds show greater vaccine efficacy compared to the conventional vaccine[13] in terms of immunogenicity (blood tests for antibodies and lymphocytes), these results should be put into perspective, as the Pfizer vaccine is only superior for influenza A strains, but not for influenza B strains. The reasons for this are not explained in the *NEJM* article.

In this article, which only considers the 18-64 age group with regard to the adverse effects of this mRNA vaccine, it is stated that "*the adverse event profiles [editor's note: related to mRNA or conventional vaccines] were similar in both groups*". However, the same article goes on to note that "*adverse events considered by the investigator to be related to the vaccine were reported in 3.3% of mod RNA recipients and 1.4% of control recipients*", which does not appear to be "*similar*".

Furthermore, although Pfizer does state in the *NEJM* publication that a total dose of 30 micrograms of vaccine mRNA was injected in people aged 18-64, there is no detail on the distribution of doses by strain.

In the same article, Pfizer notes that the mRNA flu vaccine was "*associated with more reactogenicity events*"[14] than the non-mRNA flu vaccine, but that most were "*mild to moderate*". However, the complete data show much higher figures for the mRNA vaccine than for the conventional vaccine in the table of reactogenicity at 7 days, across all age groups.

The *Fréquence Médicale* article also emphasises the reactogenicity of the vaccine, but calls for it to be reduced with a view to improving the mRNA vaccine for production. This is proof that it should not be overlooked in the current state of the vaccine.

A global trial marked by negligence

A very significant bias in this phase 3 trial is the choice of the control group. Some researchers point out that the results of Pfizer's study are "*invalid*" because the vaccine was not tested against an unvaccinated control group, but only against a conventional inactivated vaccine (also quadrivalent). "*There is no placebo group, which means that the entire efficacy claim is based on its relative efficacy compared to the influenza vaccine available at the time*," said Karl Jablonowski, PhD in biomedical informatics[15]. The independent experts also point out that "*by comparing it to a vaccine that is already in use [editor's note: the conventional vaccine], the actual rate of adverse effects is underestimated*".

The aforementioned article in *Fréquence Médicale* also deplores the "*comparison with an approved vaccine rather than a placebo*".

There are also shortcomings in terms of the doses of mRNA injected. In the phase 3 trial in people over 65, there is no data on the total dose of vaccine mRNA injected, nor on the distribution of doses by strain. The phase 1/2 trial proves that numerous dosages and combinations were tested, but the figures are hidden in the data. In any case, this demonstrates the difficulty designers had in finding a tolerable and effective dose for each strain.

On the other hand, the trial highlights that participants in the 18-64 age group had antibodies against three of the four influenza strains tested prior to vaccination, which means that these individuals had been in contact with the virus in previous years. It would have been more rigorous to seek only individuals who were free of these antibodies, or to create two subgroups, those with antibodies and those without.

Finally, on the fundamental issue of vaccine safety, the possibility of a risk of recombination between genetically modified vaccine mRNAs and circulating wild-type influenza viruses is not addressed. This is particularly important given that there are four strains of vaccine RNA in this vaccine and that the EMA (European Medicines Agency) recognises this risk between the RNA of live vaccines (authorised but not marketed in France) and the RNA of wild viruses16.

The precautionary principle not respected

How can we explain the publication of a study that only reports the estimated positive results for a segment of the population that is not particularly affected by flu complications? Meanwhile, for elderly people affected by this disease, the results indicating side effects have been excluded from this publication. Without knowing whether a link exists, it should be remembered that the annual flu vaccination market is worth several billion dollars each year.

This omission is a serious breach of the precautionary principle, as are other oversights in the trial, such as the possible recombination of viral RNA, which compromises the safety of mRNA injections.

This failure to take the precautionary principle into account is precisely what the new team at the Food and Drug Administration (FDA) in the United States is questioning. Given Pfizer's lack of rigour and concealment of data, the FDA will not approve the trial without additional data on the safety of this vaccine17.

It should be noted here that Moderna and GlaxoSmithKline (GSK) are also conducting clinical trials of an mRNA vaccine against influenza. These companies are also encountering setbacks with the same FDA18.

Furthermore, the concealment of data could lead to criminal liability for Pfizer, a company that is no stranger to the courts, "*if it can be shown that there was intentional deception, material harm or foreseeable risk, and collaboration with Pfizer to conceal the data*"19.

mRNA vaccine technology still leaves questions unanswered, particularly regarding its medium-term efficacy and long-term safety. It should also be noted that mRNA vaccines are the only vaccines for which the quantity and quality of the antigen produced cannot be controlled, as each organism reacts differently.

With regard to the mRNA vaccine against influenza, due to its great complexity (several different mRNA genetic constructs that must produce different antigenic proteins), we are still a long way from scientifically conclusive results and the essential safety requirements. As things stand, this proposed mRNA vaccine technology against influenza presents more risks than benefits.

Proposing such a vaccine seems more like a race between competitors and shows a lack of responsibility on the part of companies... which should curb politicians' enthusiasm for this RNA technology in medicine and agriculture.

- + Marc Gozlan, "L'aventure scientifique des vaccins à ARN messager", *Le Monde*, 14 December 2020.
- + Since 2020, *Inf'OGM* has published numerous articles on this subject. These can be found in the "Health" section of our website.
- + Fitz-Patrick D., McVinnie D.S., Jackson L.A. *et al.*, Protocol to "Efficacy, immunogenicity, and safety of modified mRNA influenza vaccine", page 11, *NEJM*, 7 June 2022.
- + Fitz-Patrick D., McVinnie D.S., Jackson L.A. *et al.*, "Efficacy, immunogenicity, and safety of modified mRNA influenza vaccine", *NEJM*, vol. 393, pp. 2001-2011, 19 November 2025.

- + MA: marketing authorisation.
  Marketing authorisation is requested from the various health authorities when phase 3 clinical trials are conclusive.
- + European Parliament, "Procedure 2025/0406(COD) – European Biotech Act".
- + A vaccine is a prescription medicine.
- + Fitz-Patrick D., McVinnie D.S., Jackson L.A. *et al.*, Supplementary Appendix to "Efficacy, immunogenicity, and safety of modified mRNA influenza vaccine", *NEJM*, 19 November 2025.
- + ClinicalTrials.gov, "A Study to Evaluate a Modified RNA Vaccine Against Influenza in Adults 18 Years of Age or Older", 8 May 2025.
- + *Ibid.*, table in note 8.
- + Michael Nevradakis, "Profound Breach of Trust: Pfizer Omitted Trial Data Showing Higher Mortality, Kidney Failure in Seniors Given mRNA Flu Shot", *The Defender*, 1st December 2025.
- + Philippe Montereau, "Grippe : un vaccin à ARNm plus efficace que le quadrivalent standard chez l'adulte jeune", *Fréquence Médicale*, 20 November 2025.
- + These conventional vaccines show efficacy ranging from 35% to 60% depending on the year.
- + Among the adverse effects, those of "*reactogenicity*", the property of a vaccine to produce adverse reactions in the form of an excessive immunological response, manifest themselves as fever, pain at the injection site accompanied by swelling, induration and redness.
- + Michael Nevradakis, "Pfizer Touts Success of mRNA Flu Vaccine Trial — Critics Push Back Citing Flaws, Gaps and Safety Signals", *The Defender*, 25 November 2025.
- + European Medicines Agency, "Replacement of quadrivalent seasonal influenza vaccines with trivalent vaccines in the EU" , 18 March 2024.
- + Michael Nevradakis, "FDA Won't 'Rubber-Stamp' Pfizer mRNA Flu Vaccine Without Better Safety Data,"*The Defender*, 15 December 2025.
- + Michael Nevradakis, "Pfizer touts success of mRNA flu vaccine trial — critics push back citing flaws, gaps and safety signals", *The Defender*, 25 November 2025.
  Michael Nevradakis, "FDA Announces 'Radical Framework' for Overhauling Vaccine Approval Process", *The Defender*, 16 May 2025.
  As of 5 January 2026, Moderna has filed another application for approval of an mRNA-based influenza vaccine in the United States, Europe, Canada and Australia:
  Moderna, "Moderna Announces Global Regulatory Submissions for Its Investigational Seasonal Influenza Vaccine", 5 January 2026.
- + Michael Nevradakis, "Profound Breach of Trust: Pfizer Omitted Trial Data Showing Higher Mortality, Kidney Failure in Seniors Given mRNA Flu Shot", *The Defender*, 1st December 2025.
