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Research on Covid-19 Vaccines' Effectiveness is not using Appropriate Scientific Methods

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Abstract

Global research on the Covid-19 vaccine's effectiveness is using methods that are misleading the scientific community and public opinion. There is a golden rule in medicine: to measure the effectiveness of an experimental medicine you need to have two groups. The group that will take medicine and the group that will not take medicine. You follow the health status of both groups for a few months and you will get objective results. This is the only proper methodology to verify the effectiveness of a new medicine. Articles cited from 1-5 did not use the gold rule. They develop different kinds of methodologies that all have no statistical significance. On the basis of their methodologies, they conclude that Covid-19 vaccines have a positive effect on public health. By comparing graphs of the intensity of vaccination and the rate of mortality we see that after the period of intense vaccination follows the period of higher excess mortality. Basic statistical data are confirming that Covid-19 vaccines increased the mortality rate.

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1. Introduction

Because of the high excess mortality caused by the Covid-19 virus in 2020 world's medical system under the supervision of WHO started massive vaccination end of 2020 and at the beginning of 2021 with the aim to reduce excess mortality. Several articles' conclusions are that Covid-19 vaccines decreased mortality ^{[1][2][3][4][5]}. Their research methods are not appropriate and do not respect the gold standard of science, namely, the efficacy of a massive vaccination can only be

measured by comparing the death rate of the vaccinated population with the death rate of the non-vaccinated population. Recently this research was done and it has confirmed that the vaccinated part of the global population has increased mortality rate by about 14.5% with respect to the non-vaccinated population ^[6].

In the research methodology we use, every element in the model corresponds to exactly one element in physical reality. The world is set X with n elements, and the model of the world is set Y with n models. Every element in set X has exactly one correspondent element in set Y. In physics, this methodology has given excellent results. It can also be applied in statistics and big data analysis. The entire population in a given country is set A, it has two subsets, set vaccinated and set non-vaccinated. In the set vaccinated, people are protected from covid-19 and should have a smaller mortality rate than people in the set of nonvaccinated. This means in set A, the subset non-vaccinated will be the main source of excess mortality.



Figure 1. Set A, subset vaccinated, and subset-vaccinated

With the increase of vaccination in a given time period the subset of vaccinated is increasing and the subset of nonvaccinated is decreasing. This means more people are vaccinated slower should be the mortality rate. With the massive vaccination in time, the mortality rate in set A should decrease. This hypothesis was checked by comparing the graphs of numbers of daily vaccination and the graphs of the mortality rate. The more people were vaccinated in a given time period smaller should become mortality rate in the following time period. This analysis of data was done for several states of the United States.

2. The bijective analysis of the graphs of the intensity of vaccination and graphs of mortality rate

The sources of data are the following: Our World data^[7] is used to get the number of administered doses per 100 people. These are graphs on the left. US MORTALITY data are used to see the excess mortality rate over time ^[8]. These are

graphs on the right.



The dark on the left spot is the begging of vaccination on 31 December 2020 when excess mortality was at its peak. With the increase in vaccination that reached its peak on 13 April 2021, the mortality rate has decreased. The green spot is the minimum vaccination on 10 July 2021. With the increase in vaccination from 10 July 2021 to 31 January 2022 (from green to the red spot on the left) mortality rate reached its peak on 31 January 2022. The black arrow on the left is an intense vaccination period. The black arrow on the right is the period of high excess mortality that culminated at the end of intense vaccination on 31 January 2022. With the decrease in vaccination (from red point to violet point) also mortality rate has decreased. The violet spot is 26 March 2022.

The positive correlation of vaccination in the first month of vaccination is characteristic also for some other countries^{1]}. The USA is an exception in the sense that in all other countries, this positive correlation lasted only to the end of March 2021.



The black arrow on the right is representing intense vaccination in March and April 2021. The black arrow on the right is the stable mortality in April and May 2021. The brown arrow on the left is intense vaccination in March and April 2021. The brown arrow on the right is the intense excess mortality in April and May 2021. The red arrow on the left is 31 January 2022 after intense vaccination. The red arrow on the right is the peak of excess mortality on 31 January 2022.

Data of state Alabama are confirming that when vaccination in a given period was intense in the following period the mortality rate increased. It should be the opposite, after intense vaccination in a given period mortality rate in the following period should decrease. Figure 2 indicates that with a massive vaccination, the mortality rate of the population is increasing. An analysis of all states of the US will show if Figure 2 is an exception or rule.

For Alaska, graphs do not show a significant causal correlation between the intensity of vaccination in a given period and the mortality rate in the following period.



Figure 4. Arizona

The black spot on the left and right is the beginning of vaccination on 13 January 2021. The red spot on the left and right is the peak of vaccination on March 31. The red arrow on the left indicates the end of intense vaccination on July 12. The red arrow on the right indicates the peak of mortality on the day of July 12. The blue arrow on the left indicates the end of intense vaccination on the day of 12 September. The blue arrow on the right indicates the peak of excess mortality on the day of September 14. The green spot on the right is the end of intense vaccination in 2022 on March 21, and the green spot on the right is the end of excess mortality in 2022 on Mach 21. The black arrow on the left is the end of massive vaccination on the day November 28 in 2002. The Black arrow on the right is the peak of mortality on November 29 in 2022.



The blue arrow on the left is the end of the massive vaccination on 21 January 2021. The blue arrow on the right is the peak of mortality on 18 January 2021. The red arrow on the left is the peak of the period of intense vaccination on 9 August 2021. The red arrow on the right is the peak of excess mortality on 9 August 2021. The green arrow on the left is the end of intense vaccination on 31 January 2023. The green arrow on the right is the peak of excess mortality is the peak of excess mortality on 7 February 2023.



The black arrow on the left and right is 11 July 2021. The horizontal black arrow on the left is intense vaccination in December 2021 and in January 2022. The horizontal red arrow on the right is a period of excess mortality in January and February 2022.



The black arrow on the left is the intense vaccination in November and December 2021. The red arrow on the right is a period of intense excess mortality in November and December 2021 and January 2022. In general, after the period of intense vaccination, the excess mortality rate should decrease because people should have been protected from Covid-19. In general, the result is the opposite.



Figure 8. Connecticut

The horizontal black arrow on the left is intense vaccination in November and December 2021 and January 2022. The horizontal red arrow on the right is the period of excess mortality in December 2021 and January 2022. The thin red arrow on both sides is 25 March 2022.



The horizontal black arrow on the left is intense vaccination in December 2021. The horizontal red arrow on the right is the period of excess mortality in January 2022. The thin red arrow on both sides is 1 April 2022.



The horizontal black arrow on the left is intense vaccination in December 2021. The horizontal red arrow on the right is the period of excess mortality in January 2022. The thin red arrow on both sides is 15 February 2022.



The horizontal black arrow on the left is intense vaccination in December 2021. The horizontal red arrow on the right is the period of excess mortality in January 2022. The thin black arrow on both sides is 30 March 2022.



The red arrow on the left is 30 August 2021 after intense vaccination. The red arrow on the right is a peak of the intense mortality period on 6 September 2021. The horizontal black arrow on the left is intense vaccination in January 2022. The horizontal red arrow on the right is the period of excess mortality in January and February 2022. The thin green arrow on both sides is 30 March 2022.



The black arrow on the left is intense vaccination between 12 December 2021 and 20 January 2022. The red arrow on the right is the period of intense excess mortality rate between 14 January 2022 and 14 February 2022. The green arrow on both sides is 2 April 2022.

For Idaho, graphs do not show a significant causal correlation between the intensity of vaccination in a given period and the mortality rate in the following period.



The horizontal arrow on the left is intense vaccination in November, December 2021, and January 2022. The horizontal arrow on the right is a period of excess mortality in December 2021, January 2022, and the first two weeks of February 2022. The slanted arrow on the left is 10 Mach 2022, and the slanted arrow on the right is 10 Mach 2022.



The vertical arrow that points down on the left is 10 December 2021. The vertical arrow that points down on the right is 13 December 2921. The vertical arrow that points up on the left is 12 January 2022. The vertical arrow that points up on the right is 15 January 2022. The round spot on the left is 31 March 2022. The round spot on the right is 31 March 2022.



The dark arrow on the left is active vaccination in October, November, and December 2021, and the first five days of January 2022. The red arrow on the right is the period of high mortality from 25 October 2021 to 21 January 2022. The green arrow on both sides is 14 March 2022.



The dark arrow on the left is active vaccination in November, and December 2021. The red arrow on the right is the period of high mortality in January 2022 and the first two weeks of February 2022. The green arrow on both sides is 4 April 2022.



The first black arrow on the left is intense vaccination in August 2021. The first red arrow on the right is the intense high mortality from 15 August to 15 October 2021. The second black arrow on the right is intense vaccination in December 2021. The second red arrow on the right is a period of excess mortality from 15 January 2022 to 15 February 2022. The green arrow on both sides is 27 October 2021. The red arrow on both sides is 21 March 2022.

Further analysis for other countries will not give surprises. The fact that intense periods of vaccination are followed by periods of higher excess mortality is obvious and nobody who understands the basic of science will not obey this fact.

3. Analysis of the results published in the article "Global impact of the first year of COVID-19 vaccination: a mathematical modelling study" in Lancet in 2022

Claims of this article that Covid-19 vaccines have saved millions of lives are questionable: "COVID-19 vaccination has

substantially altered the course of the pandemic, saving tens of millions of lives globally. However, inadequate access to vaccines in low-income countries has limited the impact in these settings, reinforcing the need for global vaccine equity and coverage" ^[9].

Authors said that this study has added values: "This mathematical modelling study advances previous work both in terms of scale (number of regions modelled) and in terms of quantifying both the direct and indirect impact of COVID-19 vaccination globally. We estimated the impact of vaccination up to Dec 8, 2021, by fitting COVID-19 transmission models to both reported deaths and excess mortality during the pandemic as a proxy for deaths due to COVID-19" ^[9]. This article attempts to calculate how many people would die because of the Covid-19 virus if there would be no mass vaccination program, in other words, how many people's lives were saved with Covid vaccines. The human population worldwide is depicted below as a set A that has N elements. All these elements' lives were endangered by the Covid-19 virus. With the vaccination entire population that is set A was divided into two subsets, a subset vaccinated and a subset non-vaccinated, see Figure 1.

Within The Lancet piece which is cited by many proponents of the mass vaccination program, the authors only address the "SUBSET vaccinated". The authors, funded by Gates Foundation, Gavi the Vaccine Alliance, and others calculate the extent to which the covid vaccines have protected the world's population from Covid-19, thus saving lives, but their calculations are applied only to "SUBSET vaccinated".

Their results are following: "Based on our model fit to officially reported COVID-19 deaths, we estimated that 18·1 million (95% credible interval [Crl] 17·4-19·7) deaths due to COVID-19 would have occurred without vaccinations worldwide during the first year of the COVID-19 vaccination program (Dec 8, 2020, to Dec 8, 2021). Of these, we estimated that vaccination prevented 14·4 million (95% Crl 13·7-15·9) deaths due to COVID-19, representing a global reduction of 79% of deaths (14·4 million of 18·1 million) during the first year of COVID-19 vaccination (table 1). These estimates of vaccine impact do not account for the potential under-ascertainment of deaths related to COVID-19" ^[9].

In the entire article, the authors completely avoided how "SUBSET non-vaccinated" managed the Covid-19 virus. They divided the human population into two parts and thus, make conclusions for both parts. The Watson et al quantitative model suggests 14.4 million lives were saved worldwide, without including the non-vaccinated part of the human population in their calculus. In science is a general rule, that you cannot make conclusions about something that you did not include in your research. Researchers have excluded the non-vaccinated part of the human population. It might be the case, at least with some non-immunized cohorts, this segment has managed better with the Covid-19 virus due to natural immunity, or other factors such as age, etc. have remained non-compromised. This possibility that should be taken into account is by the authors automatically excluded. They just assume bad outcomes with that entire human population.

We do not have substantial clinical results that could prove that covid vaccines are saving lives. This still is a working hypothesis, so the opposite is also possible. Covid vaccines also could save the lives of the non-vaccinated group and take the lives of the vaccinated group. While there is an accumulation of data pointing to vaccination benefits many of these claims are based on flawed, observational data packaged and presented to bolster the mass vaccination case.

Historically unprecedently a large number of serious side effects captured in VAERS suggest this alternative also is open and should be evaluated. In The Lancet piece, the authors take for granted that covid vaccines save the lives of vaccinated people; yet, scientifically, the proof for this conclusion is lacking. To see if this is true also the non-vaccinated group should be taken into elaboration equally as the vaccinated group. For both groups, the same mathematical model should be used. They could calculate for example the mortality rate (MR) for the year 2021 of both groups in percentage:

 $MR_{vaccinated} = \frac{100 \cdot vaccinated dead}{vaccinated}$ $MR_{vaccinated} = \frac{100 \cdot non \cdot vaccinated dead}{non \cdot vaccinated}$ (1) $MR_{non-vaccinated} = \frac{100 \cdot non \cdot vaccinated}{non \cdot vaccinated}$

Using this mathematical model, both groups would be equally examined and this is the only way to get objective results. According to their narrative the mortality rate MR_{vaccinated} should be much lower than the mortality rateMR_{non-vaccinated}. To get highly precise results both groups should be divided into five age groups (0-20, 21-40, 41-60, 61-80, +80) and calculations should be done for each age group. In general, the older population was more vaccinated than the younger population and older people die more frequently than younger. Calculating mortality rate in percentage for each age group separately, the Simpson effect is excluded.

Age group	MRvaccinated	MRnon-vaccinated	
0-20	MRV1	MRNV1	
21-40	MRV2	MRNV2	
41-60	MRV3	MRNV3	
61-80	MRV4	MRNV4	
+80	MRV5	MRNV5	

Table 19. Age groups for calculation of mortality rate in percentages

$$MRV_{n} = \frac{100 \cdot VACCINATED DEAD n}{VACCINATED n}$$

$$MRNV_{n} = \frac{100 \cdot NON - VACCINATED DEAD n}{NON - VACCINATED n}$$
(2)

We have several methods in statistics for equal evaluation of the impact of covid vaccination on both groups^{6]}. In general, the gold standard is that the non-vaccinated group is serving as a control group which is compared with the vaccinated group. But what is not acknowledged in the countless journals praising the mass vaccination program is that a majority of the research that addresses covid vaccine effectiveness lacks anything near the gold standard. The focus is only on how vaccines have helped the vaccinated group. The non-vaccinated group is excluded from their evaluation which is a huge failure in the research methodology that makes their results highly unreliable and useless.

This article does not respect the basic rules of scientific methodology, in this case, is the following: "When you study a

given system, you cannot divide the system into two parts, study only one part and then give conclusions about the entire system". Authors used mathematical models that have no security mechanism, they are not self-regulating in the sense that they cannot verify their exactness. In brief, there is no control group, there is no gold standard. Their results have no statistical significance and are therefore useless and misleading.

Analysis of five-month vaccination in England has confirmed that the vaccinated part of the population has increased the mortality rate by bout 14,5% ^[6]. Detailed analysis for the entire years 2021 and 2022 where calculations should be done for five age groups (0-20, 21.40, 41-60, 61-80, and above 80) will give the exact increased mortality rate due to the massive Covid-19 vaccination.

Age group	Dead D	Alive	Vaccinated
0-20 (1)	D1	A1	V1
21-40 (2)	D2	A2	V2
41-60 (3)	D3	A3	V3
61-80 (4)	D3	A4	V4
+80 (5)	D5	A5	V5

Table 20. Age groups for calculating their proportional number of vaccinated dead VD proportional

The exact mortality rate for each age group we calculate as follows:

$$VD_{Proportional} = \frac{Vn \cdot Dn}{An}$$
(3)

where $VD_{proportional}$ is the proportional number of vaccinated dead persons. According to our results the calculated $VD_{proportional}$ is always smaller than the statistical number of vaccinated dead persons $VD_{statistical}$, which means that covid vaccines increased mortality rate. Covid-19 vaccines have been developed in an extremely short time and there were no necessary studies done that would clearly confirm the safety of these vaccines. If only 1000 people that were vaccinated in January 2021 would be followed up for three months and their health would be compared with the health of the control group of the same age that was not vaccinated, it would be clear by the end of April 2021 that these vaccines are hugely damaging people health and increasing excess mortality rate. Why such a study was not done is a question that medical science will need to find the answer to in order to regain people's trust.

The proof that covid vaccines increased the mortality rate does not require high-profile scientific education. One that can compare graphs of the intensity of vaccination and excess mortality immediately understands that graphs (see graphs 2-18) are proving the direct causal correlation between the intensity of vaccination and excess mortality. There is no need for a mathematical model and calculations that would prove the fact of damage of the Covid-19 vaccination on public health. One that has eyes can observe the graph and see the truth. A detailed mathematical analysis of these graphs can be done by using the mathematical algorithm which defines causality "Excess mortality rate period happens after the

intense vaccination period" [6].

The discussion that these vaccines are more harmful to health than beneficial to health is not appropriate because no convincing clinical studies were done that would prove these vaccines are effectively protecting health as, for example, ivermectin does ^[10]. Why the WHO did not recommend ivermectin remains an open question. One thing is certain: an organization that is 80% in private hands cannot represent the interests of global public health.

One of the conclusions of Mark Skidmore's article is the following: "Turning to the primary hypothesis, a respondent's observations within his/her social circles have a significant influence on the decision to be vaccinated. Those who know someone who experienced a significant health problem from the COVID-19 illness have higher odds of being vaccinated (OR: 1.309, 95% CI 1.094-1.566). Conversely, those who know someone who had a health problem following inoculation have lower odds of being vaccinated (OR: 0.567, 95% CI 0.461-0.698). The impact of COVID-19 vaccine injury is larger than the impact of COVID-19 illness" [11]. Skidmore's article was published on 24 January 2023 and retracted on 11 April 2023. Why the article reference ^[9] was not retracted yet remains an open question. The claim that Covid-19 vaccines saved millions of lives is a myth that should be dismantled in order to protect public health.

Vaccines mRNA are increasing the risk of neurodegenerative disease and consequently also the risk of premature death: "In light of these considerations, the risk/benefit ratio for the mRNA vaccines needs to be reevaluated. With every vaccine comes a flood of spike protein released into the circulation, further advancing the potential for amyloidogenic effects and increasing the risk of future neurodegenerative disease. A comment by Kenji Yamamoto published in BMC is urging the medical community to keep track of the date of the most recent vaccination of hospital patients in order to be better able to assess what role the vaccine may have played in any manifest disease or condition. He also strongly discourages policy that promotes continued boosting of anyone other than the most at-risk patients to death from COVID-19. There is an urgent need for governments to reconsider a blind policy that assumes that repeated vaccine boosters are a valid approach to dealing with COVID-19" ^[12]. The high excess mortality in 2022 is the result of the massive covid vaccination in 2021 that has increased the mortality rate of the vaccinated population by about 14.5% ^[6]. The possibility that covid vaccines may increase the mortality rate is automatically excluded from all of the scientific literature. In their narrative people are dying only because of the Covid-19 virus, the possibility to die because of covid vaccines is automatically excluded. Statistics are adjusted in the ways that they describe the expected result. Reference [13] is a school example of this approach. Nobody is willing to calculate the excess mortality rate of the vaccinated population and excess mortality of the non-vaccinated population as it is suggested in this article and objectively evaluate the impact of covid vaccination on the mortality rate. We are back in middle-aged science where the geocentric system was meant to be the exact description of planets and the sun's motion around the Earth. All calculations were exact, nobody has a minimal doubt that the geocentric model could not be correct. Today, we have the same situation. The narrative is that Covid-19 vaccines are saving lives, but the huge numbers of heavy side effects because of covid vaccination (VAERS, EMA) which may lead to death, are not taken into consideration ^[6]. All statistics are adjusted to get such results. This is not science, this is not peer review, and this is pseudoscience in the hands of globalist politics.

4. Covid crisis is the time of cognitive death of empiricism in medicine

With the covid crisis, medical science has lost the spirit of empiricism. Articles are published about the effectiveness of vaccines, which do not have a relevant mathematical model and exclude the fact that only a control group of an unvaccinated part of the population can prove the effectiveness of vaccination against covid. Using elementary school math, we can calculate the death rate of a vaccinated subset of the population and compare it to the death rate of an unvaccinated subset of the population. No one has made this simple and effective calculation.

The spirit of empirical science born in the Renaissance is one of the brightest achievements of Mankind. It has taken the human race out of the dark early middle age of irrationality and superstition. The core of empiricism is the development of a mathematical description of the world that is verified with the experiment. Here is the cognitive power of empiricism that has intuitively chosen the bijective research methodology as its basic rule. In Newton's physics, every element in the mathematical model of the world has exactly one corresponding element in physical reality. For example, the formula for gravitational force between two physical objects:

$$F_g = \frac{\frac{m_1 \cdot m_2 \cdot G}{r^2}}{(4)}$$

where we have mass one, mass two, distance r between masses, and gravitational constant that was precisely measured by Cavendish and later by other physicists. Empirical science has linked physical reality and a model of physical reality to the extent of objectivity. When we say that science is objective, we mean that what science says, is true in its physical actuality.

We have several articles published in peer review journals that claim covid vaccines decreased mortality rate, and that with covid vaccination millions of lives were saved. When you read these articles, you see that there is no empirical bond between the mathematical model and the physical reality. Authors are claiming that covid vaccines helped the vaccinated part of the population and saved numerous lives, but nobody is comparing the mortality rate of the vaccinated part of the population with the mortality rate of the non-vaccinated part of the population. This comparison is the most reliable statistical method that respects the spirit of empirical science.

The effectiveness of a given medicine we can measure at the best of the people that did not receive the medicine. Claiming that covid vaccines have reduced the mortality of the vaccinated part of the population and that the unvaccinated part of the population has a higher death rate, without measuring it, is an unprecedented cognitive decline of empirical science.

5. Conclusions

The Covid-19 vaccination was done worldwide in an extreme rush to diminish the excess mortality rate because of the Covid-19 virus. The expected result was not achieved, and the statistical data are proving the opposite. The WHO has

failed to do its job to protect global public health. Their experts for public health should respect ordinary scientific procedures of the gold standard where first you check up on a new medicine on a limited group of people and when being sure that medicine is working well you consider it makes sense to use it worldwide. All research that concluded that Covid-19 vaccines were successful and they diminished mortality rates have no support in the analysis of the basic statistical data.

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