

A brief estimation of deaths in Germany caused by short-term adverse reactions to SARS-CoV-2 vaccines

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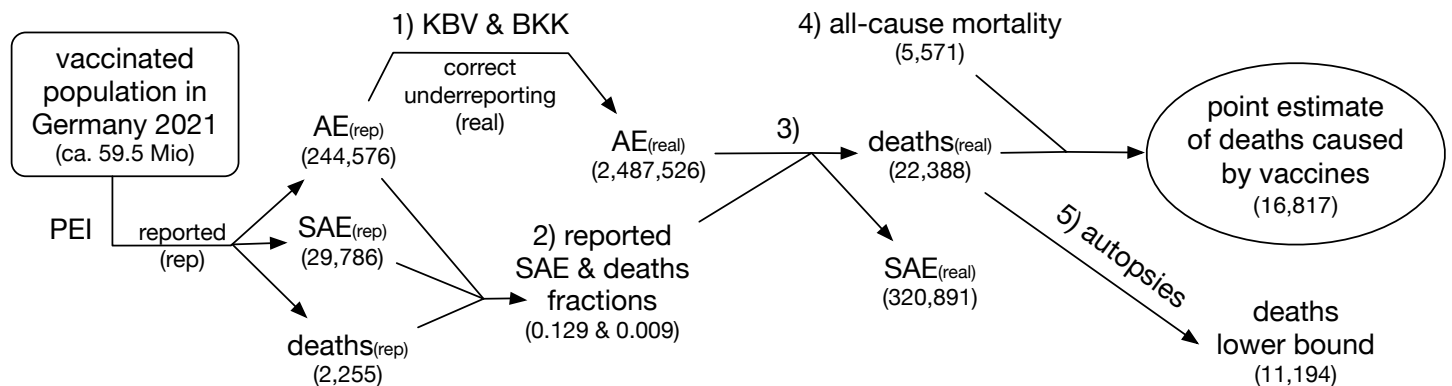
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1 Abstract

While the efficacy of the newly developed mRNA and vector vaccines against SARS-CoV-2 have been widely advertised, their harm-to-benefit ratio still remains widely ignored. Though, reports of possible side effects are piling up. The most severe of those side effects is a sudden and unexpected death, with liability issues inducing strong incentives to communicate potentially associated mortalities always aligned with the particular motives and interests. Accordingly, reliable estimates of how many deaths might have been actually caused by the vaccination are still missing up to date, to the best of our knowledge, in Germany at least. Here, we fill this void and provide such an estimate for Germany during the course of 2021. Thereto, the number of deaths reported by the Paul-Ehrlich-Institut to have occurred within the group of people suspectedly struck by a vaccine-induced adverse event is scaled by the factor of under-reporting, based on health insurance reports, and finally corrected by known all-cause mortality. Our point estimate for the year 2021 alone reaches a total of 16,817 (short-term) deaths caused by SARS-CoV-2 vaccination. Taking independent autopsy reports into account, the estimate of 11,194 deaths is the lower bound. This report may serve as a pivot for further investigations in this matter.

13 Graphical abstract



16 Zusammenfassung (German)

Während die Wirksamkeit der neu entwickelten mRNA- und Vektor-Impfstoffe gegen SARS-CoV-2 weithin beworben wird, bleibt ihr Schaden-Nutzen-Verhältnis weitgehend unbeachtet. Doch die Berichte über Nebenwirkungen häufen sich. Die schwerwiegendste dieser Nebenwirkungen ist der plötzliche und unerwartete Tod. Haftungsfragen erzeugen starke Antriebe, um die entsprechenden Sterblichkeiten immer im Sinne zugehöriger Interessen und Motivlagen in die Öffentlichkeit zu tragen. Eine verlässliche Schätzung, wie viele Todesfälle tatsächlich durch diese Impfungen verursacht worden sein könnten, fehlt jedoch bis heute, aus unserer Sicht zumindest für Deutschland. Wir füllen hier nun diese Lücke und liefern eine solche Schätzung für das Jahr 2021, basierend auf den vom Paul-Ehrlich-Institut (PEI) vermeldeten (Verdachts-)Todesfällen, indem wir den

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Faktor der Untererfassung durch das PEI auf Basis der Behandlungsabrechnungen der Kassenärzte bei deren Bundesvereinigung (KBV) ermitteln, und die solcherart hochgerechneten Verdachtsfälle schließlich mittels der bekannten, alle Ursachen umfassenden Hintergrundsterblichkeit korrigieren. Unsere Punktschätzung für das Jahr 2021 allein erreicht die Gesamtzahl von 16.817 Todesfällen, welche als unmittelbare Folge aufgrund einer SARS-CoV-2-Impfung auftraten. Berücksichtigt man zudem bestehende Autopsieberichte, ergibt sich eine untere Grenze von 11.194 Impf-ursächlichen Todesfällen. Unsere Analyse kann und soll als Ausgangspunkt für weitere Untersuchungen in dieser Sache dienen.

1. Introduction and motivation

In a recent study [1], the authors calculated a harm-to-benefit ratio of mRNA vaccines, delivered to young people in the United States, by analysing data from the ‘Centers for Disease Control and Prevention’ (CDC). For the vaccinated cohort, they documented an absolute reduction in the risk of CoViD-19 hospitalisation of no more than 0.002-0.003% compared to the unvaccinated cohort. In other words, over 30,000 subjects had to be vaccinated to prevent a single case of CoViD-19 hospitalisation. Concomitantly, the authors calculated that 18.5 cases of *severe* adverse events (SAE), which in part resulted in hospitalisation, were accompanied by each a case of prevented CoViD-19 hospitalisation. Approximately 8%-25% of the SAE resulted in myopericarditis, a life-threatening condition. Their harm-to-benefit ratio of 18.5 well matches [2] who analysed just a specific selection of *serious* AE in the original clinical trial data (ratios above 1 in all vaccines), as well as our own findings [3] in the earliest published data of some pivotal clinical trials of SARS-CoV-2 (mRNA or vector) vaccines: ratios between 0.6 and 25 for *severe* AE at least, with 3.6 for explicitly *serious* AE conditions in one mRNA vaccine. Further papers, e.g. [4], likewise document a significant risk of myopericarditis inflicted by mRNA and vector vaccines. As a note, more than 75% of the CDC-documented SAE resulted in other conditions requiring hospitalisation, with myopericarditis not being the only life-threatening AE condition induced by SARS-CoV-2 vaccination.

Naturally, some of the life-threatening SAE result in death. In Germany, AE induced by vaccines are registered on a ‘to be notified’ basis, and have been regularly reported by the Paul-Ehrlich-Institut (PEI), during 2021 at least. In that year—or, more exactly, from the beginning of the vaccine campaign on 27/12/2020 until the end of June 2022—the PEI reported 3,023 deaths suspected to be due to SARS-CoV-2 vaccination. As a side note, this number is basically a *conditional* death count, namely, within the group of people suspected to show an AE, which is a fatality selection widely different from the commonly used, simple *unconditional* (i.e. *all-cause*, see further below) death count. It has been concluded from autopsies [5, 6] that up to 80% [7] of suspectedly vaccine-related deaths were indeed caused by SARS-CoV-2 vaccination. It is also well documented in general [8] and across countries [9] that AE registration procedures suffer from dramatic under-registration, with well beyond 90% of drug-related AE not being registered by authorities [10, p. 30].

In view of the uncertainties mentioned, this paper aims to report a reliably estimated number of deaths, which were actually *caused* by vaccines against SARS-CoV-2 infection, in Germany over the year 2021. Data basis and starting point are (i) the suspected AE counts registered in the ‘to be notified’ data base run by the PEI, and (ii) the AE fractions of the sub-counts of SAE and deaths, respectively. We then scale the PEI number of suspected AE, while retaining the SAE and death fractions, by means of the number of medical treatments due to AE as reported by the German-wide health insurance accountant of medical treatments, the ‘Kassenärztliche Bundesvereinigung’ (KBV) [11], and by one of the German health insurance companies (‘BKK ProVita’) [12], which had independently analysed treatment data of a sub-population. We further estimate the number of expected all-cause deaths within the AE sub-group of Germans, and contrast the suspected versus the expected deaths, the excess being our point estimate of deaths caused by vaccination. Autopsy data [5, 7, 6, 13, 14] allow us to eventually estimate a lower boundary to the number of deaths actually caused by SARS-CoV-2 vaccines.

2. Methods and results: data handling and calculations

This section provides a detailed explanation of the Graphical Abstract above, with the occurring numbers corresponding to the paragraphs herein.

First, we calculate both the SAE and the death fraction of the number of AE suspected to be due to SARS-CoV-2 vaccines, according to the latest two associated safety reports of the PEI [15, 16]. While the *absolute* AE, SAE, and death numbers are under-estimated in the PEI reports [10, p. 30], the *fractions* therein can well be considered characteristic parameters of the German SARS-CoV-2 vaccination campaign. From the beginning of the campaign on December 27th, 2020 until June 30th, 2022, 323,684 suspected cases of subjects suffering an AE were counted, 43,911 cases of suspected SAE, and 3,023 people suspected to have died from vaccination [16]. Adopting the one-year-after report [15] as a second data source (244,576 AE, 29,786 SAE, and 2,255 deaths), we calculate a mean SAE fraction of 12.9% and a mean death fraction of 0.9% within the group of people having suspectedly suffered an AE.

Second, the issue of AE under-reporting by the PEI can be resolved using data provided by the KBV: In their response [11] to a request by a Member of Parliament (‘Bundestag’), the KBV acting as the public health insurance accountant reported close to 2.5 million subjects who had consulted a physician in 2021 due to a vaccine-related AE. The KBV reporting reflects about 90% of German physicians who claimed compensation for their treatments referring to the ICD code U12.9 (‘International Statistical Classification of Diseases and Related Health Problems’; unspecified adverse reactions associated

with the inoculation by COVID-19 vaccines) for over 90% of the AE cases. These are 10.2 times more AE cases than reported by the PEI. This KBV-to-PEI ratio is in line with the wide-spread, practically general degree of under-reporting [8] on a voluntary or ‘to be notified’ basis (which, e.g., applies to the PEI requesting German physicians based on their assessment), as it is with a published comparison [9] of registration rates across European countries. Moreover, the KBV data are in almost perfect alignment with likewise ICD code data reported by one German health insurance [12] already in late 2021, owing to the initiative of a leading insurance manager who ended up being kicked out of office on the very same day as going public.

Third, now taking the ICD-code-based (KBV) number of AE (2,487,526) as a realistic estimate of persons suspectedly struck by an AE due to SARS-CoV-2 vaccination during the year 2021, we can calculate, by multiplication with the corresponding PEI-based fractions, the number of persons having suspectedly suffered a *severe* AE (320,891) or even died (22,388).

Fourth, we correct the number of people, who have suspectedly died after receiving the vaccination (22,388), by the expected annual *all-cause* mortality within the observed time window. To find how many persons must have died due to all-causes anyway, three further pieces of information are required: (i) the annual all-cause mortality rates of all age cohorts represented within those vaccinated; (ii) the time span after injection during which the PEI ‘accepts’ a fatality of a suspected AE case to be possibly due to the vaccine, 50 days [15, p. 9] (later [16]: data given for 30 days); and (iii) the vaccination quota of each age cohort.

The number of people *expected* to die for any reason (all-cause mortality) within a defined time span can be computed by

$$\begin{aligned} n_{T,ac} &= n_{pop} \cdot r_{ann} \cdot T \\ &= n_{pop} \cdot (a_{young} \cdot r_{young} + a_{old} \cdot r_{old}) \cdot T \end{aligned} \quad (1)$$

with n_{pop} being the referenced number of persons constituting the population, r_{ann} the annual all-cause death rate, and T a fraction of time, which would be 1 for a whole year. For higher accuracy, the population can be divided into age cohorts—e.g. particularly *older* (≥ 60 years of age) and *younger* (< 60 years)—with their respective cohort-specific fractions (a_{young} and a_{old}) and death rates ($r_{young} = 0.0019$ and $r_{old} = 0.041$), which were adopted from [17]. These rates were computed by dividing the number of people within these age groups [18] by the corresponding number of reported deaths [19].

By the end of 2021, about 59.5 million (of total 83.4 million) Germans had been “fully” vaccinated [15]. Neglecting therein, due to both their fraction and their annual death rates being small, the 2.4 million youngsters below 18 years of age, we can calculate the number $n_{50d,ac}$ of all-cause deaths to be expected within the 50 days after the ‘date of injection’:

$$n_{50d,ac} = 2,487,526 \cdot \left(\frac{36.0}{59.5 - 2.4} \cdot 0.0019 + \frac{21.1}{59.5 - 2.4} \cdot 0.041 \right) \cdot \frac{50}{365} = 5,571 \quad (2)$$

The difference of $16,817 = 22,388 - 5,571$ between estimated suspected and expected deaths represents the *excess* deaths that are thought to be caused by the vaccine itself. In other words, according to our estimation, 75% of suspected deaths were due to unexpected cause.

Fifth, other sources allow to estimate a lower bound of our point estimate of 16,817 vaccine-induced short-term fatalities. The numbers of AE, SAE, and deaths counted by the PEI are labelled “suspected”. This label is due to the PEI not checking for specific causes of the fatal health issues, which is, however, possible through autopsies. Indeed, there are very few, albeit hard, histo-chemical autopsy data that verify a direct link between SARS-CoV-2 vaccination and death. Autopsy reports from a German team of pathologists document a range from originally at least 33% [5] to, given more recently, 80% [7] for the vaccination being the cause of death in suspected cases. While this original/initial value of 33% had well matched the range 30-40% reported [13] already three months earlier by a another German team of pathologists, the more recent value [7] of 80% matches the 75% based on our excess-to-all-cause estimation. Note the critical remarks [20] having been made on this latter work [7] to possibly contain some methodical issues. A more recently published value of the second team dropped to 5 of 35 [14], i.e. just 14%. However, they had then searched for evidence of only and exactly one conventional fatal mechanism, namely, myocarditis. Due to their extremely limiting search focus, we omit their results in a preliminary estimation of a percentage of vaccination being causative among suspected deaths; as a start, we estimate this factor from preliminary autopsy data as the arithmetic mean of 33% [5], 35% (mean of 30-40%) [13], and 80% [7], i.e. about 50%. With this, we can give an estimate of the lower bound of vaccine-induced short-term fatalities, namely, half of the 22,388 suspected deaths, i.e. 11,194.

3. Discussion

Eventually, we have arrived at what we initially aimed for: The 2,255 deaths from vaccination, officially reported by the PEI [15, 16], were scaled to 22,388 with respect to suspected under-reporting, indicated by the KBV and BKK statistics [11, 12], and corrected by roughly 25% to 16,817 due to the expected all-cause mortality [17]. As a comparison, 2,562 persons died in road accidents in Germany in 2021 [21], i.e. the same number of deaths occurred due to SARS-CoV-2 vaccination

in a day as road deaths in a week. For another comparison, 16,817 excess deaths due to SARS-CoV-2 vaccination during 2021 correspond to two thirds of the excess deaths of the most severe influenza epidemics in Germany between 2000 and 2019, namely 25,100 in the season 2017/18 according to the RKI [22]. Last, boiled down to a single small number, the *excess mortality rate* σ_{vacc} , defined as the ratio between observed (here: ‘suspected’) and expected mortality (22,388/5,571), equals $\sigma_{vacc} = 4$, i.e. the probability of dying from any cause within the vaccinated population, if being struck by an AE, is quadrupled compared to the overall population. A synopsis of all input and output (estimated) numbers is given in Table 1.

Table 1: Counts n_{AE} of suspected *adverse events* (AE), n_{SAE} of suspected *severe adverse events* (SAE), and n_{Xd} ($X = 30, 50$; ‘d’ means ‘days of monitoring’) of suspected *deaths* in Germany due to SARS-CoV-2 (mRNA or vector) vaccination as documented by the PEI [15] during 2021 (more exactly, for the campaign 27/12/2020-31/12/2021), with computed n_{SAE} and n_{Xd} fractions of n_{AE} , as well as *excess mortality ratio(s)* $\sigma_{Xd,vac}$ of SARS-CoV-2 vaccination; in mid 2022, the PEI reported [16] a n_{30d} one-time count. **Counts** and the two n_{AE} **fractions derived therefrom** are printed in **bold font**, further calculated numbers otherwise. Each n_{AE} fraction value is the arithmetic mean of the values calculated from the two counts, until end of 2021 and mid 2022, respectively. — All $n_{Xd,ac}$ values have been calculated using Eq. (1) with varied $n_{pop} = n_{AE}$ and T values, i.e. correspondingly replacing 2,487,526 and $\frac{50}{365}$ in Eq. (2), while r_{ann} being a constant (value 0.01635 in parentheses of Eq. (2)). — The number $n_{Xd,exc} = n_{Xd} - n_{Xd,ac}$ of suspected *deaths in excess of expected all-cause deaths* is our final estimate of the number of *deaths caused by vaccination*. — The vaccine-induced *excess mortality ratio* $\sigma_{Xd,vac} = \frac{n_{Xd}}{n_{Xd,ac}}$ quantifies the increased, in relation to regular all-cause mortality, probability to die, *given* being struck by an AE. — Among 83.4 million Germans, until 31/12/2021, about 59.5 million persons had been vaccinated twice at least (vaccination quotas: [26, Abb. 17]; age cohort strengths: [18]), with about 148.8 million doses [15] inoculated, and until 30/06/2022, 63.6 million persons [27, Abb. 19],[18], with 182.7 million doses [16]. — See text for a lower $n_{50d,exc}$ bound estimated from autopsy data.

data source:		PEI ₂₀₂₁ [15]	PEI _{mid2022} [16]	n_{AE} fraction	KBV ₂₀₂₁ [11]
n_{AE}		244,576	323,684		2,487,526
n_{SAE}		29,786	43,911	0.129 (12.9%)	320,891
n_{50d}	$[n_{30d}]$	2,255 [1,391]	3,023 [1,865]	0.009 (0.9%)	22,388 [13,812]
$n_{50d,ac}$	$[n_{30d,ac}]$	548 [329]	725 [435]		5,571 [3,343]
$n_{50d,exc}$	$[n_{30d,exc}]$	1,707 [1,062]	2,298 [1,430]		16,817 [10,469]
$\sigma_{50d,vac}$	$[\sigma_{30d,vac}]$	4.1 [4.2]	4.2 [4.3]		4.0 [4.1]

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136 3.1. A brief comparison with non-German reports

137 Our basic assumption is that the count (244,576) of AE registered (practically only by physicians) in the PEI-run database
 138 in 2021 [15] divided by the count (2,487,526) of patients AE-treated (ICD code U12.9: well over 90% of all treatments) by
 139 German physicians (as compensated by public health insurance and registered by KBV, covering roughly 90% of treatments
 140 in Germany) is an estimate (0.0983) of the factor of under-reporting generally observable [8, 10] in AE registration databases,
 141 and particularly in Germany during the ‘SARS-CoV-2 era’. A comparison [9] of German with Luxembourgian and Estonian
 142 AE registration rates (them second to the ‘winner’ Netherlands) reveals almost identical ratios of 0.092. Thus, our assumption
 143 of a 10.2-fold ($= \frac{1}{0.0983}$) under-reporting of AE in Germany stands on solid grounds. Accordingly, we can treat the count of
 144 KBV-registered AE patients to be an estimate much closer to the actual number of AE (even more, a sound count of *persons*
 145 definitely struck) than the AE count given by the PEI.

146 A current study has estimated the number of deaths caused by SARS-CoV-2 vaccines in the USA to be between 217,330
 147 and 332,608 [23]. These authors assumed that 51% of the population had been vaccinated and the fraction of people that
 148 had suffered a SAE within the group of people showing a suspected AE was 13%, with the latter number perfectly matching
 149 the fraction of 12.9% reported by the German PEI. In absolute numbers, this US study thus estimated that two million US
 150 citizens would have been suspected to suffer a SAE. Accordingly, the excess mortality rate within the group of US citizens
 151 suspected to show an AE would be more than nine times higher than the US-common all-cause mortality, compared to the
 152 quadrupled rate in Germany. Acknowledging the common fact of under-reporting [8], and the different registration processes
 153 of suspected AE data, as well as, mainly, vaccines being somehow differently confected for administration to US recipients
 154 than to Germans, the numbers from [23] well fit our present calculations.

155 If we assume that not every German who had suspectedly been struck by an AE saw a physician for treatment, and if we
 156 further assume that the vaccine batches [24] inoculated in Germany had not been of qualities significantly different from those
 157 administered in the Netherlands, then the factor of under-reporting of suspected AE in Germany would be the ratio between
 158 Dutch and German frequencies of safety reportings [9], namely, $\frac{701}{38} = 18.4$ instead of 10.2 determined as the KBV-to-PEI
 159 factor above; this factor of 18.4 would correspond perfectly to the reported median percentage of under-reporting, 94% [8].
 160 Accordingly, our point estimate of deaths in Germany caused in the short term by SARS-CoV-2 vaccines in 2021 would scale
 161 up to 30,337 ($= \frac{18.4}{10.2} \cdot 16,817$), and the number of suspected SAE to 578,862, the latter number being about 1% of those
 162 Germans vaccinated until the end of 2021 (59.5 million). Note that our estimated *lower bound* of deaths by SARS-CoV-2

vaccination in the short term likewise scales with the factor of under-reporting, i.e. with 18.4 instead of 10.2, the lower bound would rise to 20,187.

3.2. Final notes and conclusions

It is worth noting, that the KBV itself rates ICD codes as representing harmless events – because not complying with the criteria formulated for an AE ‘to be notified’ to the PEI by a physician – in an obvious attempt to attenuate their own data of 2.5 million adverse events after vaccination in the year 2021 [11]. Despite this, in the exact same document an impressive increase of vaccine-related ICD code registration by physicians is given: For the years 2016 to 2020, the number of AEs per vaccination is 0.0029, or 0.3%. In 2021, this number is 0.016 or 1.6%, a more than 5-fold increase of adverse events. The CoViD-19 vaccination campaign suggested people to get vaccinated two times or more, so the rate for a vaccine induced adverse event *per subject* increased almost 10-fold in 2021. Eventually, it has been found in a study [25] surveying employees’ days absent in response to their full vaccination (second dose) that 10.5% of them were unable to work for at least *two* days after the injection of the (mRNA) vaccine (‘BNT162b2’) that inflicted the *least* AE; it caused at least *one* day of absence in 22.7%.

It is also and again worth noting that the PEI traces suspected death cases for only 50 days after the date of injection [15, p. 9]. Then, in the mid 2022 PEI report [16], suspected deaths were also given for a shorter ‘monitoring interval’ after injection, namely, for only 30 days. Interestingly, these two counts given in [16], $n_{50d} = 3,023$ and $n_{30d} = 1,865$, perfectly reflect time-linear accumulation of suspected deaths between days 30 and 50. Therefore, the number $n_{50d,exc} = 16,817$ of *excess* deaths suspected *within 50 days* after vaccination can be seen as a reliable point estimate of the number of deaths *caused by SARS-CoV-2 vaccination within short terms* in Germany in 2021.

As a further note, the corresponding population-averaged excess mortality rate σ_{NF} specific for deaths conditional to the population (a sub-group of all Germans) of NAA-test-positive persons (the putatively ‘SARS-CoV-2 infected’; ‘NAA’ for ‘nucleic acid amplification’, including PCR-based methods; index $_{NF}$ for ‘NAA-test-positive fatality’) has been $\sigma_{NF} \approx 2.7$ for each of the whole-year periods 2020 and 2021, and $\sigma_{NF} \approx 4.3$ for the respective ‘flu seasons’ 2020/2021 and 2021/2022 [17]. Accordingly, for a German who is suspected to be struck by an AE due to SARS-CoV-2 vaccination, the quadrupling ($\sigma_{vacc} \approx 4$) of the likelihood to die is a higher increase in mortality risk than if having received a positive NAA (usually PCR) test ($\sigma_{NF} \approx 2.7$), averaged across a year and all age cohorts. As a further fact, there has not been any significantly increased mortality risk in the NAA-test-positive younger than 60 years ($\sigma_{NF} \leq 1$) [17], i.e. $\sigma_{NF} \approx 2.7$, averaged over a year, is solely due to the risk being increased beyond the common level by SARS-CoV-2 infection of those older than 60 years. In contrast, the risk to die due to vaccination is equally increased across age cohorts, if not more pronounced in the younger. We wonder, why these basic epidemiological values of ‘excess mortality rates’ seemingly have been completely overlooked by the German authorities (like the PEI and ministries), institutions, and public health scientists.

Certainly, physiological processes are induced by mRNA or vector vaccines that have immediately fatal consequences in only a sub-group of persons being particularly sensitive to these processes; accordingly, this immediate effect of vaccination vanishes as a measurable phenomenon in the population when a mass vaccination campaign ends. Observing the upcoming years and decades will bring to light (if systematic sampling will be undertaken, employing sound scientific techniques like systematic autopsies), whether and how significantly SARS-CoV-2-vaccine-induced mortality shows up in the long term wake of the world-wide vaccination campaign in 2021 (plus 2022).

Competing interests

We have no conflicts of interest.

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