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How Many Deaths Can Statistically Be Attributed to Anti-SARS-CoV-2 Injections? An Analysis of German Health Data from 2021

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Abstract

While the efficacies of the newly developed mRNA and vector vaccines against SARS-CoV-2 have been widely advertised, their harm-to-benefit ratio remains almost completely ignored, though reports of possible "side effects" (some of them lethal) keep piling up. The most severe of those adverse events is sudden death. Until now, to the best of our knowledge, in Germany at least reliable estimates of how many deaths may actually have been caused by SARS-CoV-2 vaccination are still missing. 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 persons suspectedly affected 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 best estimate for the year 2021 is that 16,817 deaths were caused by SARS-CoV-2 vaccination within the short-term observation period of 50 days after the last injection of a vaccine. Taking independent autopsy reports into account, the estimate of 11,194 deaths is a lower bound. Our hope is that this report may serve as a pivot for further investigations of the questions addressed here.

Keywords: *severe adverse event; autopsy; all-cause mortality*

The Research Plan

Our objective, in this paper, is to estimate the number of German residents who died due to SARS-CoV-2 vaccination in the campaign during the year 2021. We build our analysis only on data acquired, managed, and reported by the German governmental authorities and semi-governmental institutions — in particular, we use, in the first instance, the data provided by the Paul-Ehrlich-Institut (PEI), which is more or less the German counterpart to the USA's Food and Drug Administration (FDA). We also use data from the German bureau of statistics (Destatis) and the German public health insurance institutions. The procedural path is simple: we take the number of

suspected adverse events (AEs), as publicly reported by the German governmental agency for vaccine approval, the PEI, as primary data input. In the remainder of this paper, the term AE always implies its suspected nature. The PEI's AE database operates on a "to be notified" basis: physicians are bound by law to notify the PEI of an AE, if they suspect or diagnose an AE that goes beyond "commonly expectable reactions". Two associated safety reports by the PEI, (Cichutek, 2021; Cichutek, 2022), which reflect the AEs reported up to December 31, 2021 and June 30, 2022, respectively, constitute our primary points of reference.

To compensate for the well-known under-reporting of AEs to the PEI (Behles et al., 2017, p. 30), we use an *independent* source for the number of AEs — namely, the number of medical treatments due to AEs reported by physicians to obtain compensation from the insurance institutions. About 90% of all treatments by physicians in Germany are compensated by law through an assortment of public health insurance institutions; the latter share a German-wide accounting agency for these medical treatments, the Kassenärztliche Bundesvereinigung (KBV). In June 2022, in response to a freedom-of-information request by a German Member of Parliament, the KBV publicly reported (Gassen, 2022) the number of AE treatments indicated by ICD code U12.9 of the *International Statistical Classification of Diseases and Related Health Problems* which refers to unspecified adverse reactions associated with the injection of SARS-CoV-2 (mRNA or vector) vaccines. The KBV-reported number of U12.9 (AE) treatments in fact represents *persons*, any one of whom may have had more than one AE, so the appearance of that code in any record represents a lower bound for the number of AEs counted as such by the PEI. It is noteworthy that the PEI is bound by law since 2020 to request the KBV data to monitor potential public health "safety" (actually, danger) signals, but has never done so up to the time of this writing.

Our procedural path to the research objective — to estimate the number of German people who died due to SARS-CoV-2 vaccination during the year 2021 — is to assume that we must take the ratio between the numbers of KBV-accounted AEs and PEI-reported AEs, respectively, to be a reasonable empirical measure of under-reporting by the PEI. Our second assumption is that the AE fractions of *severe* AEs (SAEs) and AE-*associated deaths*, both of which are separately reported by the PEI, must also be adjusted for under-reporting to the same degree by the KBV data, which exactly come from treatments of AEs. Like an AE, an SAE, or even the death of a person with an AE, is reported by the PEI as being merely "suspected" of possible causation by a SARS-CoV-2 vaccination. Therefore, keeping in mind the two assumptions we have just stated, we scale up both the PEI count of SAEs and the AE-associated deaths by applying the KBV-to-PEI AE ratio as a reasonable measure of the factor of AE under-reporting to the PEI, with the actual fact of under-reporting being recognized by them (Behles et al., 2017, p. 30).

To arrive at a reasonable statistical estimate of the number of German people who died *due to* SARS-CoV-2 vaccination during the year 2021, we must subtract from the adjusted (up-scaled by the PEI-to-KBV AE ratio) number of deaths that can be reasonably associated with AEs, whatever deaths that were *expected due to all causes* within the PEI's "observation period" which was 50 days after any SARS-CoV-2 mRNA injection. Summing it all up, the difference between the number of deaths estimated to have occurred after one or more doses of SARS-CoV-2 vaccine in Germany during 2021 and the ones that would have been expected to occur without any doses is our targeted estimate (deaths *due to* the vaccines). Taking into account the age-stratified vaccination quota, our reasoning is that all deaths occurring in the sub-group of persons with an AE exceeding the number of deaths expected in accordance to the known *all-cause* mortality in the German population (Destatis: Gude, Burg, & Brand, 2022a, 2022b), must be regarded as a reasonable statistical estimate (a measure) of deaths owing to (*due to*) SARS-CoV-2 vaccination during the time frame of 2021.

Additionally, we performed three validity checks regarding our estimate of deaths due to SARS-CoV-2 vaccination:

(i) The first check was against *earlier* (February 2022) and *independent* U12.9 AE treatment counts. One such count was uncharacteristically provided by one of the managers of a German public health insurance institution — specifically, Betriebskrankenkasse (BKK; Schöfbeck, 2022a, 2022b) — that makes use of the accounting agency KBV. As many as 10 million Germans are insured by BKK. It is noteworthy that BKK's count of AEs was explicitly indicated to have been *physician-confirmed* (treatment option "G").

(ii) We further checked our calculated suspected-to-expected AE death ratio by comparing it to values found through studies using multiple autopsies.

(iii) We also compared the fraction of the adjusted (up-scaled) SAEs in the German population with the corresponding fractions published in the scientific literature by the vaccine producers who have claimed that the reported data represent findings from their phase-3 clinical trials during late 2020.

An essential question arises with regard to the striking discrepancy (10-fold, see our results) between the number of AEs directly notified by physicians to the PEI and the, by contrast, high number of U12.9 AE treatment-accounted persons. One thing is for sure: the incentive for a German physician to get compensation for a U12.9 treatment in the year 2021 has been *minimal* (and for notifying even *less so*) for four reasons.

(a) Diagnosing or treating a U12.9 AE does not provide a German physician any financial benefit over and above the insurance compensation for any other basis for treating a patient. As a side note, this heavily contrasts to physicians having performed mass vaccinations on weekends, and also to the enormous over-compensation of hospital operators for nursing intensive-care patients diagnosed with COVID-19 as compared to those suffering from any other illness.

(b) A shortage of resident, in particular family, doctors, who treat the majority of German patients, has accumulated over several decades in Germany, meaning that those having practiced in 2021 already had more patients than they could readily handle.

(c) Notifying (reporting to) the PEI costs a physician approximately half an hour, which is much longer than the time provided for compensation by health insurance regulations for actually treating a patient. Moreover, the time spent in filling out the form for PEI is *not compensated* at all.

(d) The vast majority of German physicians — like *all* their established commissions, federations, and associations — not only promoted SARS-CoV-2 vaccines, but the physicians themselves injected many doses of them in their patients. Accordingly, there was a significant inherent reluctance of the German medical profession to admit to having possibly done harm to some patient by registering a U12.9 report for that person. The disincentivization was even more severe if the physician knew that the patient who was suspected of being injured by one or more doses of a SARS-CoV-2 vaccine had a pre-existing health problem increasing that person's susceptibility to a SARS-CoV-2 vaccine injury. Given (a)-(d), there is ample reason to infer that the under-reporting by the PEI, as suggested by the KBV (and BKK) data, was even more extreme than our best estimate in the present paper.

As a last note, the physicians are the fulcrum of the vaccination campaign and for the data used in this paper: informing patients before their consent, injecting the vaccines, possibly notifying the PEI of an AE, and balancing accounts with the health insurance entities by claiming compensations for vaccine injections as well as AE diagnoses and treatments. In Germany, there are about 420,000

physicians in action, with a little more than half of them being employed in hospitals, about another 40,000 family doctors, and about 120,000 additional specialised resident doctors.

Background Known from the Start

In a recent study analyzing data from the Centers for Disease Control and Prevention (CDC), Bardosh et al. (2022, Table 1, top-right) estimated, for a representative US clinical trial group of twice-vaccinated persons who also got a third dose of vaccine ("first booster"), 18.5 cases of "serious AEs" (deemed more severe than "severe AEs"[1]) kept just 1 person infected by SARS-CoV-2 out of the hospital (a withering harm-to-benefit ratio at 18.5), with an unknown number of vaccine-induced hospitalizations (due to AEs) not even taken into account in this ratio. Referring to the actual frequencies of serious AEs and SARS-CoV-2/COVID-19 hospitalizations, a staggering minimum of 31,207 persons would have to be "boostered" with SARS-CoV-2 vaccines to prevent 1 case of SARS-CoV-2/COVID-19 hospitalization for which an absolute risk reduction of no more than 0.003% was documented.

According to further research by Bardosh et al. (2022, Table 1, bottom), in young adult males in particular, between 8% (1.5/18.5 = 0.08 for 18 to 29 year olds, clinically diagnosed *and* lab or technically confirmed) and 34% (6.3/18.5 = 0.34 for 16 to17 year olds) of the serious AEs were found to involve myo- or pericarditis, respectively, or both, which are life-threatening conditions.[2] Notably, the threatening level (percentage of occurrence in all cases of serious AEs) of myo/pericarditis is the highest in young males, in those 30 years and older it is approximately 10 times lower than the extreme in the 16 to17 year olds (i.e. about 3.5%), and again generally about 5 times lower in females of the same respective ages. Taking thus myo-/pericarditis cases as a basis of estimation, at least 2% of all serious AEs across the whole vaccinated population are life-threatening, however, in the 16 to 17 year old vaccinated males the myo/pericarditis category accounts for every third serious AE.

The harm-to-benefit ratio at 18.5 found by Bardosh et al. (2022) in a US-representative population for serious-AEs-from-the-boostered-vaccines divided by hospitalizations-from-SARS-CoV-2-that-were-supposedly-prevented-by-the-vaccine was distinctly greater than calculated by Fraiman et al. (2022). The latter researchers, however, had analyzed just a *specific selection* of serious AEs in the original data of two phase-3 clinical trials (showing harm-to-benefit ratios above 1 in both of the most used SARS-CoV-2 vaccines: 4.4 in BNT162b2 by Pfizer and 2.4 in mRNA-1273 by Moderna). The harm-to-benefit ratio found by Bardosh et al. (2022) was also greater than in our own findings (Mörl, Günther, & Rockenfeller, 2022) from the earliest published data of phase-3 clinical trials of SARS-CoV-2 (mRNA or vector) vaccines: we found harm-to-benefit ratios between 0.6 and 25 for SAEs, and 3.8 for explicitly *serious* AEs by BNT162b2 (Polack et al., 2020). No wonder, our findings are in remarkable agreement with Fraiman et al. (2022), as the data are basically from the same trials. In summary, the harm-to-benefit analyses by Bardosh et al. (2022), Fraiman et al. (2022), and us (Mörl, Günther, & Rockenfeller, 2022) provide consistent findings of the (un-)safety profiles of SARS-CoV-2 vaccines, mRNA vaccines in particular.

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[1] Note that, in clinical terminology, *serious* AEs are an even *more severe* sub-category of AEs than *severe* AEs, the latter abbreviated as SAEs in this paper.

[2] As a further note, myo-/pericarditis conditions are not the only life-threatening AEs induced by SARS-CoV-2 vaccination.

AEs come with a distinct bandwidth of symptoms (Tuuminen, Suominen & Gulbrandsen, 2023), some SAEs are life-threatening, some even result in death. In Germany, as we have already noted above, AEs possibly being induced by vaccines are registered on a "to be notified" basis in a reporting system run by the PEI. That governmental agency asks German physicians for notification concerning any AE beyond what is common and expected in vaccine reactions based on their diagnostic experience. The number of AEs, SAEs, and associated deaths were regularly reported by the PEI to the public at least until the end of 2021, and again six months later at the end of June 2022. From December 27, 2020, the beginning of the vaccination campaign, until the end of June 2022, the PEI reported 3,023 deaths associated with SARS-CoV-2 vaccination. As a side note, this number is basically a *conditional* death count, namely, within the group of persons showing an AE. This is a *conditional* fatality count based on selection, not the commonly used, simple *unconditional* (i.e. *all-cause*) death count. We will have more to say about this below, where we also show from autopsies (Burkhardt, 2022) that up to 80% (Ausic, 2022) of vaccine-associated deaths were indeed caused by SARS-CoV-2 vaccination. It is also well documented in general (Hazell & Shakir, 2006), and across multiple countries (Vaccines Editorial Office, 2021; Walach, Klement, & Aukema, 2021a, 2021b, 2022), that requiring authorities "to be notified" in some AE registration procedures has invariably resulted in dramatic under-registration, with well beyond 90% (Hazell & Shakir, 2006) of drug-associated AEs not being registered with or accounted for by authorities at all.

In view of the afore-mentioned facts, our goal in this paper is to determine a reliable and reasonably valid estimate of deaths that occurred in Germany during the year 2021, which were actually *caused* by vaccines against SARS-CoV-2 infection. Our data basis and starting point are (i) the AE counts registered in the "to be notified" database run by the PEI, and (ii) the AE fractions of the sub-counts of SAEs and deaths, respectively. We then scale the PEI number of AEs, while retaining the SAE and death fractions, by means of the number of medical treatments due to AEs as reported by the German-wide accounting agency KBV (Gassen, 2022). To eventually reach our target estimate of the number of deaths *caused* by SARS-CoV-2 vaccines, we additionally estimate the number of *all-cause* deaths that are *expected* within the number of AE-affected persons and within the PEI's observation period of 50 days after any SARS-CoV-2 vaccine administration. The estimated number of deaths caused by SARS-CoV-2 vaccines, our target number, is then the difference between the AE-associated deaths according to the PEI (times the KBV factor of under-reporting) and the estimated expected deaths within the number of AE-affected persons reported by the KBV. This method of contrasting a death count within any group of persons selected by a "side condition", e.g. being vaccinated and affected by an AE, or being tested positive by a PCR test, versus the number of expected all-cause deaths within that group has been worked out and explained in detail in Rockenfeller, Günther, & Mörl (2023). Autopsy data (Ausic, 2022; Baethge & Schmedt, 2021; Burkhardt, 2022; Schwab et al., 2023) allow us ultimately to estimate an ultra-conservative lower boundary to our target number.

Methods and Results: Data Handling and Calculations

This section provides a detailed explanation of our workflow as illustrated in Figure 1. The steps in our research plan are numbered beginning at the left and proceeding to the right. Each numbered step is explained in the following paragraphs:

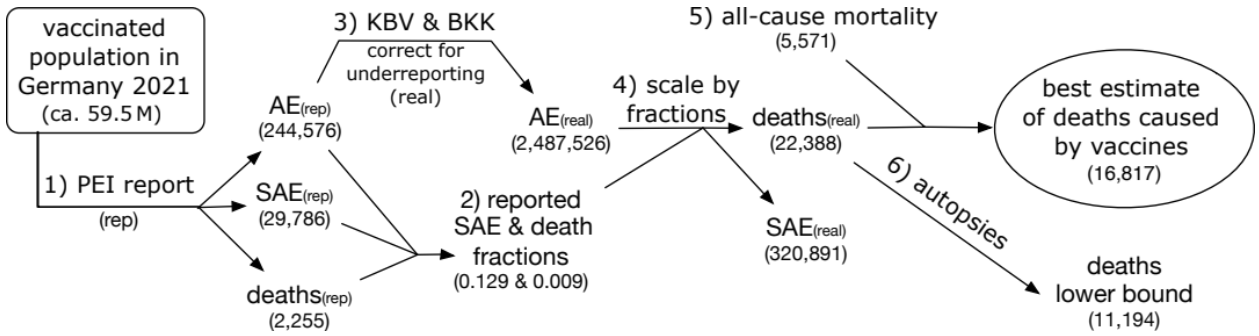

Figure 1. Workflow to calculate how many Germans were expected to die due to SARS-CoV-2 vaccination. 2) The PEI-reported percentage fractions of SAEs or deaths in the number of AEs are 12.9% or 0.9%, respectively. 3) From health insurance sources (KBV and BKK), it is apparent that absolute AE counts by the PEI are under-reported by a factor 10.2, i.e. KBV-reported AEs accounted for 2,487,526. 4) Assuming the PEI-reported fractions to likewise apply to KBV-reported AEs yields more reliable estimates for SAEs (320,891) and vaccine-associated deaths (22,388) after vaccine injection. 5) Subtracting the expected all-cause mortality (5,571) within the PEI's observation period of 50 days, the remaining fatalities (16,817) can be attributed to the vaccine as a best estimate. 6) A lower bound of causally related deaths (11,194) can be estimated by exploiting autopsy findings.

1) First, we extract the AEs, SAEs, and the deaths associated with the SARS-CoV-2 vaccines, according to the latest two associated safety reports from the PEI (Cichutek, 2021; Cichutek, 2022).

2) Second, we calculate both the SAEs and the death fraction of the number of AEs due to SARS-CoV-2 vaccines. While the *absolute* AE, SAE, and death numbers are under-estimated in the PEI reports (Behles et al., 2017, p. 30), the *fractions* therein can well be considered characteristic parameters of the German SARS-CoV-2 vaccination campaign.[1] From December 27, 2020, the beginning of the campaign, until June 30, 2022, a total of 323,684 cases of persons affected by an AE, 43,911 cases of SAEs, and 3,023 persons suspected to have died from vaccination (Cichutek, 2022) were counted. Given the one-year-after report (Cichutek, 2021), which indicated 244,576 AEs, 29,786 SAEs, and 2,255 deaths until only December 31, 2021, we calculate the following arithmetic mean values of the fractions over both data sources (Table A1): within the group of persons being affected by AEs, 12.9% were reported to be affected by SAEs, and 0.9% were reported to have died.

3) Third, the issue of AE under-reporting by the PEI can be resolved using data provided by the KBV: In their response (Gassen, 2022) to a request by a Member of Parliament ("Bundestag"), the KBV acting as the public health insurance accounting agency reported close to 2.5 million persons who had consulted a physician in 2021 due to a vaccine-associated AE. The KBV reporting accounts for about 90% of German physicians who claimed compensation for their treatments referring to the ICD code U12.9 for over 90% of the AE cases. These amount to 10.2 times more

[1] The cause-of-death statements are completed by physicians in Germany, and we have already outlined their (weak) incentives (and their strong disincentives, see the numbered list on page 3) to notify the PEI of AEs or SAEs, respectively, in our opening section "The Research Plan". These incentives have been and are definitely not stronger in case of inspecting and labelling a deceased person in the statement as "likely to have died due to SARS-CoV-2 vaccination". In addition, we are not aware of any unambiguous clinical criteria to distinguish a SARS-CoV-2 vaccination as a (suspected) cause of death from other possible causes. Moreover, the PEI criteria for finally associating reported fatalities with SARS-CoV-2 vaccination are non-transparent, except for having to occur within 50 days after an injection (a non-clinical criterion). Yet, exactly the same two entities (physicians and the PEI) determine the selection of reporting, whether an AE, an SAE, or an AE-associated death, with about the same (weak) incentives to report either, very likely even weakest for reporting deaths. This gives us reason to assume that the fractions of SAEs and AE-associated deaths within the PEI-reported data are do not make reporting the severe outcomes SAEs, or deaths, more likely than AEs.

AE cases than reported by the PEI. This KBV-to-PEI ratio is in line with under-reporting (Hazell & Shakir, 2006) on voluntary or "to be notified" bases (Vaccines Editorial Office, 2021; Walach, Klement, & Aukema, 2021a, 2021b, 2022) across European countries. Moreover, the KBV treatment numbers are in almost perfect alignment with the ICD code U12.9 numbers reported by one German health insurance institution (Schöfbeck, 2022a, 2022b) in late 2021. It is worth noting here that the physicians are the sole source of both U12.9 treatments and AE notifications to the PEI. We have commented on the 2021 physicians' incentives and disincentives in our opening section (see the list on page 1028 above).

4) Fourth, now taking the ICD-code-based (KBV) number of AEs (2,487,526) as a realistic estimate of persons affected by an AE due to SARS-CoV-2 vaccination during the year 2021, we can estimate, by multiplication with the corresponding PEI-based fractions, the number of persons probably affected by an SAE (320,891), or who died (22,388).

5) Fifth, we subtract from the number of persons, who have died after receiving the vaccination in the year 2021 (22,388), the number of AE-affected persons who were expected to die within that year and within the time span after dose injection, in which the PEI accepts a death to be associated with an AE (observation period), all based on reliably registered annual *all-cause* mortality (Gude, Burg, & Brand, 2022a, 2022b). This method of estimating *excess* mortality under any "side condition" (here, e.g. within a group of vaccinated and AE-affected people) has recently been applied by us (Rockenfeller, Günther, & Mörl, 2023) to another condition (within PCR-test-positive people).

To find how many persons would have been expected to have died "due to all causes" among all those who were identified with an AE, three further pieces of information are required: (i) the annual all-cause mortality rates of all age cohorts that were vaccinated; (ii) the PEI's post-injection observation period, which is 50 days (Cichutek, 2021, p. 9; and see their 2022 report), data also given for observing just a 30-day period (see Table A1); and (iii) the vaccination quota of each age cohort.

The number of persons $n_{T,all}$ *expected* to die for any reason (all-cause mortality) within a defined time span can be estimated by

$$n_{T,all} = n_{pop} \cdot r_{ann} \cdot T = n_{pop} \cdot \left(a_{young} \cdot r_{young} + a_{old} \cdot r_{old}\right) \cdot T \qquad (1)$$

With n_{pop} being the referenced number of persons constituting the specific sub-population of interest, r_{ann} the annual all-cause death rate, and T a time fraction of a year, where 1 would represent 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 relative fractions (a_{young} and a_{old}) of n_{pop} and death rates (r_{young} = 0.0019 and r_{old} = 0.041), which were adopted from Rockenfeller, Günther, and Mörl, (2023). Each cohort's annual all-cause death rate was calculated by dividing the number of deaths reported in a year (Gude, Burg, & Brand, 2022b) within the cohort (Gude, Burg, & Brand, 2022a) by the number of persons constituting the cohort (its size).

By the end of 2021, about 59.5 million Germans (out of the total population at 83.4 million) were reported to have been "fully" vaccinated (Cichutek, 2021). Setting aside, the 2.4 million youngsters below 18 years of age, due to both the fraction of the whole population they represent and their annual death rate both being small, we can calculate $n_{50days,all}$, the number of all-cause deaths, expected within the 50 days after the last reported date of injection:

$$n_{50days,all} = 2{,}487{,}526 \cdot \left(\frac{36.0}{59.5-2.4} \cdot 0.0019 + \frac{21.1}{59.5-2.4} \cdot 0.041\right) \cdot \frac{50}{365} \quad (2)$$
$$= 2{,}487{,}526 \cdot 0.01635 \cdot \frac{50}{365}$$
$$= 5{,}571$$

Because any vaccine-associated death counted by the PEI is from the sub-population affected by AEs (count n_{AE}), $n_{pop} = n_{AE} = 2{,}487{,}526$ holds for our estimation of expected deaths, with the PEI value of 244,576 simply replacing (adjusting and in effect up-scaling) the KBV number of all those reported to have been AE-treated under ICD code U12.9. Our estimate of the number of vaccine-attributed deaths is then the difference 16,817 = 22,388 − 5,571 between the estimated number of vaccine-associated deaths (see Table A1: PEI-to-KBV-up-scaled n_{AE} , i.e. 2,487,526, multiplied by the PEI-provided death fraction of n_{50days}, i.e. 0.009, which comes to 22,388) and the number of 5,571 expected deaths within n_{AE} persons affected by an AE. In other words, we estimate the number of *excess* deaths within these n_{AE} persons, and attribute this excess to the vaccines, i.e. view it to be an estimate of the number of deaths caused by (due to or owing to) the vaccine itself. Hence, according to our estimation, 75% of the (suspected) deaths must be attributed to the SARS-CoV-2 vaccines — an estimated 16,817 vaccine-attributed deaths in 2021.

6) Sixth, other sources allow us to estimate a lower bound of our best estimate of 16,817 vaccine-induced fatalities in the short-term. We recall: the numbers of AEs, SAEs, 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 unambiguous, albeit very few, 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% (Burkhardt, 2022) to, more recently, 80% (Ausic, 2022) 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 already three months earlier by another German team of pathologists (Baethge & Schmedt, 2021), the more recent value (Ausic, 2022) of 80% comes closer to the 75% based on our own estimate of the increase in all-cause mortality that we attribute to SARS-CoV-2 vaccination. Still, critical remarks by Orient (2022) addressed to Ausic (2022) on the basis of methodological issues should be taken into account. A more recently published value of a follow-up research team dropped the estimate to 5 out of 35 (Schwab et al., 2023), or just 14%. However, in doing this, the second team searched for evidence of only one conventional cause of death, namely, myocarditis. Due to this extreme narrowing of focus, we dismiss their results in our preliminary estimate of the percentage of deaths that can reasonably be attributed to SARS-CoV-2 vaccination. As a starting point, from the relevant autopsy data, we use the arithmetic mean of 33% (Burkhardt, 2022), 35% (mean of 30-40%; Baethge & Schmedt, 2021), and 80% (Ausic, 2022) — which is approximately 50%. With this, we can give an estimate of the lower bound of vaccine-caused fatalities over the short term of 50 days of observation. It comes to about half the 22,388 suspected deaths, or 11,194.

Discussion

To arrive at our target as shown in Figure 1, we adjusted (by up-scaling) the 2,255 deaths in 2021, which have been officially reported by the PEI (Cichutek, 2021; Cichutek, 2022) to be vaccine-associated because of their occurrence within an observation period of 50 days after injection, to 22,388. This up-scaling compensates the PEI's under-reporting of AEs by replacing their AE record with the *corresponding* KBV record which accounts for (covering 90% of the AEs) U12.9 treatments

within the German population by physicians (Gassen, 2022; Schöfbeck, 2022a, 2022b). From these up-scaled 22,338 AE-associated deaths, we subtracted (Rockenfeller, Günther, & Mörl, 2023) roughly 25% due to expected all-cause mortality, to eventually arrive at an estimate of 16,817 deaths being our (best) estimate of deaths due to (caused by) SARS-CoV-2 vaccination during 2021.

To appreciate this death toll, we note that 16,817 excess deaths per year correspond to two thirds of the excess deaths of the most severe influenza epidemics in Germany between 2000 and 2019. There were 25,100 in the season 2017/18, according to calculations by the Robert-Koch-Institut (RKI; Buda et al., 2019), which is the German counterpart to the USA's CDC. Converting our best estimate to a single small number, the *excess mortality ratio* σ_{vacc} of the German 2021 SARS-CoV-2 vaccination campaign, defined as the ratio between observed mortality (here: suspected or diagnosed by physicians) and expected mortality, equals $\sigma_{vacc} = 22{,}388/5{,}571 \approx 4$. That is, the probability of dying from any cause within the vaccinated population, *and if falling in that group being affected by an* AE, was approximately quadrupled in comparison to the risk of dying of any other cause during 2021. A synopsis of all input and output (estimated) numbers is given in Table 1; for a cross-check of PEI data (our input), Table 1 additionally encompasses numbers that are calculated from the PEI reporting AE-associated deaths for a shorter observation period after injection (30 days).

Comparison with Non-German Reports

Our basic assumption is that the 2,487,526 U12.9 AE-treated patients, reported by the KBV, divided by 244,576 SARS-CoV-2-vaccination-associated AEs, reported by the PEI in 2021, yields 10.2 as an estimated factor of under-reporting. Such under-reporting is generally observable in AE registration databases (Behles et al., 2017; Hazell & Shakir, 2006).

A comparison (Walach et al., 2021b, figure 1; Walach et al., 2021a, figure. 1) of the German numbers with AE registration rates in Luxembourg and Estonia (running a little behind the Netherlands) reveals very similar ratios at 10.9. Thus, our assumption of a 10.2-fold AE under-reporting in Germany appears to be confirmed. Accordingly, we can treat the count of physician-suspected or physician-diagnosed, and thus KBV-registered, AE patients to be much closer to the actual number of AEs (even more so, for *persons* definitely injured) than the AE counts given by the PEI.

Current research has estimated the number of deaths caused by SARS-CoV-2 vaccines up to January 16, 2022 in the USA to be between 217,330 and 332,608 (BMC Infectious Diseases Editorial Office, 2023; Skidmore, 2023a, 2023b). These authors assumed that 51% of the US population (331.5 million) had been vaccinated, and the fraction of persons who had suffered an SAE within the group of persons affected by an AE was 13%, with the latter number matching the fraction of 12.9% reported by the German PEI. In absolute numbers, these US research studies thus estimated that 2 million US citizens would have been affected by an SAE, which corresponds to an SAE versus total AE fraction of 118 in 10,000 persons ($10{,}000 * 2/(0.51*331.5) \approx 118$) within the US population. Accordingly, the *excess mortality ratio* within the group of US citizens affected by an AE would be more than 9 times higher than the US-common all-cause mortality, compared to the quadrupled risk (see above) in Germany. Again, acknowledging the known fact of under-reporting (Hazell & Shakir, 2006), and the diverse processes for registering AEs, as well as the supposition that the lots of vaccines used in the USA must be somewhat different in contents from those in Germany, the numbers from Skidmore (2023b) are in close agreement with our present estimations.

Also, There Are Data from phase-3 clinical trials

Given the estimated fraction of SAEs occurring after vaccination against SARS-CoV-2 in the US population, we may ask what is the corresponding value in Germany based on our scaling from PEI to KBV data, as summarized in Table A1 of the **Appendix** following immediately after the list of **References**. The answer is given in Table 1 above, along with a cross-check by the fraction values that can be calculated from the published data from the phase-3 clinical trials of five SARS-CoV-2 (mRNA and vector) vaccines (Baden et al., 2021; Logunov et al., 2021; Polack et al., 2020; Sadoff et al., 2021; Voysey et al., 2021). The result again surpasses our KBV-based claim.

A value of 119 SAEs per 10,000 persons should have been expected in Germany from the phase-3 trial data (which is extremely close to the value 118.3 value observed in the USA), whereas our PEI-scaling by KBV data yields 54 SAEs per 10,000 persons in Germany. Hence, our SAE estimate is evidently conservative, which renders our best estimate of 16,817 deaths caused by vaccination likewise conservative.

We will not comment here on the corresponding SAE fractions in the control groups of the phase-3 vaccine trials. Those may well be worth further in-depth investigations, but such would go beyond the scope of this paper. The fraction of *serious* AEs *of special interest* found by Fraiman et al. (2022) in the phase-3 trial data is a factor of 3 to 4 times smaller than in the SAE category in the same data (see the first two data rows in Table A1). This is not surprising at all, as *serious* AEs *of special interest* are first of all the close-to-life-threatening sub-category of SAEs (*serious* being more severe than the *severe* sub-category of AEs), and a specific sub-selection of events within *serious* AEs on top of that.

Our estimated KBV-based factor (10.2) of under-reporting by the PEI may still be too low. If we assume that not every German who had been affected by an AE saw a physician for treatment, and if we further assume that the vaccine batches administered in Germany had not been of qualities significantly different from those administered in the Netherlands (Yeadon et al., 2023), then the factor of under-reporting of AEs in Germany would be the ratio between Dutch and German frequencies of safety reports (Walach et al., 2021b, figure 1; Walach et al., 2021a, figure 1) — specifically, 701/38 = 18.4 instead of 10.2; this factor of 18.4 corresponds closely to the reported median percentage of under-reporting at 94% (Hazell & Shakir, 2006) for which the factor would be 100/(100-94) ≈ 16.7. Accordingly, our best estimate of deaths in Germany caused in the short term by SARS-CoV-2 vaccines in 2021 would scale up to 30,337 (= (18.4/10.2)*16,817), and the number of SAEs to 578,862, the latter number being about 1% of those 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 20,193.

As a comparison for the SAE fractions calculated here, with 148.8 million doses of SARS-CoV-2 vaccines injected in Germany in 2021 (Cichutek, 2021) and our best estimate of 16,817 deaths caused by them (Table A1), the corresponding number of deaths per 10,000 doses is (16,817/148,800,000) * 10,000 ≈ 1.1, and (16,817/59,500,000) * 10,000 ≈ 2.8 per 10,000 persons vaccinated. Accordingly and accepting that only a *serious* AE *of special interest* represents a *serious* AE relevant to evaluate SARS-CoV-2 mRNA vaccines (Fraiman et al., 2022; that is, assuming that roughly every fifth *serious* AE is associated with the vaccine — compare their vaccinated-placebo difference at 11 in 10,000 with the KBV's 54 in 10,000, Table A1), about one of 11/2.8 ≈ 4 persons affected by a *serious* AE *of special interest*, i.e. 25% of them, must have died in Germany. Alternatively referring to the PEI fractions of SEAs and deaths (Table A1, 0.9%/12.9% ≈ 0.07), and taking subtraction of the estimated all-cause deaths into account, 5.2% of those affected by SAEs have

Table 1
Numbers (Fractions) of SAEs per 10,000 Persons *Vaccinated* (and in the *Control* Groups: Numbers in Curly Brackets) for Five mRNA or Vector SARS-CoV-2 Vaccines, in Each Case According to the First Paper Published on the Safety and Efficacy Data Gathered in the Phase-3 Clinical Trial Studies (see "Data Source" in Column 4 from Left)⋆

Vaccine	Company	% In Germany (Cichutek, 2022)	Data Source	*Severe* AEs (SAEs)	*Serious* AEs	*Serious* AEs *of Special Interest*
BNT162b2	Pfizer/BioNTech	74	(Polack et al., 2020, fig. 3, Tables S3, S5)	111 {64}	58 {51}	28 {18}
mRNA-1273	Moderna	17	(Baden et al., 2021, Tables S8, S10)	154 {133}	61 {59}	57 {42}
Ad26.COV2.S	Johnson&Johnson/Janssen	2	(Sadoff et al., 2021, Tables 2, S7)	21⋆⋆ {10⋆⋆}	38⋆⋆⋆ {44⋆⋆⋆}	
Sputnik	Biocad	0	(Logunov et al., 2021, Tables 2, S4)†		27 {42}	
AZD1222	AstraZeneca	7	(Voysey et al., 2021)	145 {157}		
			Germany-weighted means:	**119 {81}**	**58 {52}**	**33 {22}**
KBV			**(Gassen, 2022)**	**54**		

⋆ "Placebos" were specified as injections in the control groups of the trials of the first three vaccines, by Pfizer/BioNTech, Moderna, and Johnson & Johnson/Janssen. In the third column, the percentage fraction of administered vaccine doses is given for Germany; for four of the vaccines, the fraction of the (more severe) category *serious* AE is also available; the numbers to calculate the fractions in this table are directly taken from Mörl, Günther, & Rockenfeller (2022, Table 1; see that reference for details, remarks, and explanations about the studies and numbers extracted from it), i.e. the SAE (and *serious* AE) fractions are — adopting exactly the symbols used in Mörl, Günther, & Rockenfeller (2022, Table 1) — $N_{SAE,vac}/N_t$ *10,000, and $N_{SAE,com}/N_t$ *10,000 for the *control* groups (in curly brackets); the in-depth study by Fraiman et al. (2022, sec. 3.2) has analyzed the phase-3 clinical trial data of the first two vaccines with respect to the fractions of *serious* AE *of special interest*; the SAE fraction for the vaccinated part of the German population estimated through PEI-to-KBV up-scaling is given in the last row (see Table A1 where [320,891/59,500,000] * 10,000 ≈ 54).
⋆⋆ "AEs of interest, . . ." plus "AEs occurring more frequently . . ." plus otherwise from "SAE considered related to vaccination".
⋆⋆⋆ "Any SAE not related to COVID-19"; note: these investigators abbreviated serious AE as "SAE".
† These investigators only report serious AEs.

died (2.8/54 ≈ 0.052; numerator from Table A1, see just above, and denominator from Table 1). We compare these death fractions to what Bardosh et al. (2022) have estimated as life-threatening events from (i) serious AEs in a Pfizer/BioNTech randomized "first booster" clinical trial and (ii) myo/pericarditis frequencies in the Israel's "booster" campaign (see our section "Background Known from the Start" above): in at least 2% of serious AE cases, a life-threatening condition occurred. However, this latter percentage seems to be too low by at least an order of magnitude, as of course not every myo/pericarditis condition has a death outcome, and the severity of "serious" should lie somewhere between "severe" (SAEs) and "serious, of special interest". Therefore, the factor of under-reporting of myocarditis cases in Israel's "booster" campaign must have been very similar to what we have found for the PEI data, namely, 10 at least, but probably even higher. We emphasize that this inference comes solely from combining what is, in our view, the most reliable analysis of the phase-3 clinical trial data (Fraiman et al., 2022) with the PEI-to-KBV adjustment for the under-reporting in German (PEI) AE data.

Final Words and Conclusion

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 of which the PEI was supposed "to be notified" by a physician — in an obvious attempt to attenuate their own data of 2.5 million AEs after vaccination in the year 2021 (Gassen, 2022). Despite this, in the same document, an impressive increase is recorded for vaccine-associated ICD code registrations by physicians. For the years 2016 to 2020, the number of AEs per vaccination was reported as 0.0029, or 0.3%. In 2021, this number was 0.016, or 1.6%, more than a 5-fold increase in AEs. The SARS-CoV-2 vaccination campaign urged and even coerced people to get vaccinated multiple times, so it should be unsurprising that the rate for vaccine-induced AEs *per person* increased almost 10-fold in 2021. Eventually, it has been found in studies (Ziemann & Görg, 2021, Tuuminen, Suominen & Gulbrandsen, 2023) surveying employees for days absent after vaccination (second or last 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 *fewest* AEs; it nevertheless caused at least one day of absence in 22.7% of recipients.

It is again worth noting that the PEI supposedly keeps track of AE-associated deaths for only 50 days after the date of injection (Cichutek, 2021, p. 9). Then, in the mid 2022 PEI report (Cichutek, 2022), associated deaths were also given for only 30 days. Interestingly, the counts reported in (Cichutek, 2022) for the two observation periods are n_{50days} = 3,023 and n_{30days} = 1,865, thus, there is a near perfect linear increase in deaths, when the observation period is increased from 30 to 50 days. This is another reason why 16,817 can be seen as a reliable estimate of the number of deaths caused by SARS-CoV-2 vaccination in the short term, focusing particularly on 50 days after an injection in Germany during the year 2021. As a last note, this linear increase also demonstrates that the limitation of the observation period to, e.g., 50 days by the PEI is an arbitrary, purely formal choice. Deaths are extremely likely to be caused by vaccination months or years after the injection, i.e. in the long term. For example, myocarditis is generally known to statistically shorten the life span (Kim et al., 2023), which likewise holds distinctly true for Creutzfeldt-Jacob patients injected with SARS-CoV-2 vaccines (Perez, Moret-Chalmin, & Montagnier, 2023).

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Appendix

Comparing the Excess Mortality Ratio of the Conditions "Being Affected by an AE" and a "Positive Result on a PCR-Test"

The *excess mortality ratio* $\sigma_{NAA,cond}$ of a group of persons (population) exposed to any side condition (e.g being vaccinated and affected by an AE or having received a positive PCR test) is $\sigma_{cond} = n_{cond}/n_{condall}$. The number n_{cond} is the death count (i.e. a *measurement*) within the group, and $n_{condall}$ is the number of *expected* (*model-based*) *all-cause* deaths for a given group-size and composition. In relation to regular all-cause mortality, the *excess mortality ratio* σ_{cond} quantifies the increase in probability of dying with whatever the given "side *condition*" may be.

The age-cohort-averaged *excess mortality ratio* $\sigma_{NAA,pos}$ specific for deaths conditional to the sub-group of all Germans who received a positive NAA (SARS-CoV-2) test in the years 2020 and 2021 (the putatively "SARS-CoV-2 infected"; NAA abbreviates "nucleic acid amplification", including PCR tests) has been $\sigma_{NAA,pos} \approx 2.7$, and $\sigma_{NAA,pos} \approx 4.3$ for the flu seasons 2020/2021 and 2021/2022 (Rockenfeller, Günther, & Mörl, 2023). Accordingly, for a German who is affected by an AE associated with a SARS-CoV-2 vaccination, the quadrupling ($\sigma_{vacc} \approx 4$, see bottom row of Table A1) averaged across a year and all age cohortsof the all-cause likelihood to die is a higher increase in mortality risk than if having received a positive NAA test ($\sigma_{NAA,pos} \approx 2.7$). Furthermore, there has not been any significantly increased mortality risk in the NAA-test-selected-and-positive younger than 60 years ($\sigma_{NAA,pos}$ H 1; Rockenfeller, Günther, & Mörl, 2023), i.e. $\sigma_{NAA,pos} \approx 2.7$, averaged over a year, is solely due to the risk of the NAA-test-selected-and-positive older than 60 years being increased beyond the regular all-cause level. In contrast, the risk of death by vaccination is at least equally increased across age cohorts, and may even become more pronounced in the younger cohorts. Yet, to the best of our knowledge, none of the basic epidemiological calculations reported here in this paper regarding *excess mortality ratios* have even been calculated much less discussed by German authorities (like the PEI and ministries), other institutions, or public health scientists before now.

Table A1

Numbers of Adverse Events, Severe Adverse Events and Deaths Associated with Adverse Events as Reported by the German Authority for Drug Safety, the Paul-Ehrlich-Institut and, independently, by Kassenärztliche Bundesvereinigung (German Accounting Agency for Billing Medical Treatments by Registered Resident Physicians). From These Numbers, the Vaccine Induced Excess Mortality Ratio Can Be Calculated Showing that Persons Affected by an Adverse Event Have a Quadrupled Mortality Rate.

		PEI$_{2021}$ (Cichutek, 2021)		PEI$_{mid2022}$ (Cichutek, 2022)		PEI's fraction of n_{AE}	KBV$_{2021}$ (Gassen, 2022)	
n_{AE}		**244,576**		**323,684**			**2,487,526**	
n_{SAE}		**29,786**		**43,911**		**0.129 (=12.9%)**	320,891	
n_{50days}	$[n_{30days}]$	**2,255**	[1,391]	**3,023**	**[1,865]**	**0.009 (=0.9%)**	22,388	[13,812]
$n_{50days,all}$	$[n_{30days,all}]$	548	[329]	725	[435]		5,571	[3,343]
$n_{50days,exc}$	$[n_{30days,exc}]$	1,707	[1,062]	2,298	[1,430]		*16,817*	[10,469]
$\sigma_{50days,vacc}$	$[\sigma_{30days,vacc}]$	4.1	[4.2]	4.2	[4.3]		4.0	[4.1]

*Left from the vertical line (except last row): PEI counts of AEs (n_{AE}), SAEs (n_{SAE}), and AE-associated deaths (n_{Xdays}), with X = 30, 50 indicating days of post-injection observation used by PEI for association; counts from two PEI reports are listed, the first (Cichutek, 2021) summarizing AE data for the campaign from December 27, 2020 through December 31, 2021, the second (Cichutek, 2022) through June 30, 2022; PEI **counts** as well as the **SAE and death fractions of n_{AE} derived therefrom** are printed in **bold font**, further calculated numbers otherwise; each fraction value is given as the arithmetic mean from the two PEI reports; in mid 2022, the PEI reported (Cichutek, 2022) an additional one-time count n_{30days} for an observation period reduced to 30 days, the corresponding count (**bold font**) and calculated numbers are given in square brackets; among 83.4 million Germans, until December 31, 2021, about 59.5 million persons had been vaccinated at least twice (see vaccination quotas discussed by Wenchel and Wieler, 2022a, Abb. 17); age cohort strengths per Gude, Burg, and Brand, 2022a), with about 148.8 million doses (Cichutek, 2021) injected, and until June 30, 2022, 63.6 million persons (Wenchel & Wieler, 2022b, Abb. 19; Gude, Burg, and Brand, 2022a), with 182.7 million doses (Cichutek, 2022). Right from vertical line: U12.9 treatments (n_{AE}) reported by the KBV (Gassen, 2022) printed in **bold font**; corresponding SAEs (n_{SAE}) and 50-day death counts (n_{50days}) are calculated by multiplying KBV's n_{AE} with the value of the PEI's fraction of n_{AE} one row to the left; the value of $n_{50days,exc}$ (framed and printed in *italic* font) in the second but last row of the KBV column is our target estimate: the number of deaths caused by vaccination, calculated as the difference between the numbers of *AE-associated deaths* (n_{Xdays}) and *expected all-cause deaths* ($n_{Xdays,all}$); the latter have been calculated using Eq. (1) with $n_{pop} = n_{AE}$, r_{ann} = 0.01635 (see Equation 2), and T equaling 50/365 or 30/365, respectively. Last row: the vaccine-induced *excess mortality ratio* $\sigma_{Xdays,vacc} = n_{Xdays}/n_{Xdays,all}$ quantifies the increase in probability of dying in relation to regular all-cause mortality, given that the person is affected by an AE. Comments on these results can be found in this **Appendix**.

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Supplementary Material to Mörl, Günther, and Rockenfeller (2023) in Three Parts

Table of Contents

Overview of the Three Parts of These Supplementary Materials

We list here some documents from Germany, which have served as the bases of our calculations and which, at the time of publication of our paper on Thursday, December 7, 2023 at about 06 pm Greenwich Mean Time, might not be displayed at all on the respective webpages, or may not be available for long after this paper appears in print.

Supplementary Materials Part 1 consist of the historical and current numbers of adverse events (AEs) reported by the Kassenärztliche Bundesvereinigung (KBV) which is by law an umbrella organization of all health insurance companies in Germany. As most of German citizens have (again by law) a contract with one of the listed health insurance companies, the presented statistics comprise data regarding almost all Germans, who have been vaccinated. The table in Supplementary Materials Part 1 shows a tremendous increase in the number of AEs in 2021 compared to the years 2016-2020 (in the middle column, the number of inoculations: "Anzahl Impfungen"). Note that the number 2,487,526 for the year 2021 is the number of persons (German: "Anzahl Patienten", i.e. number of patients) affected by AEs. This leaves open the question of whether any patient may even have seen a physician twice or more times due to multiple AEs during 2021.

Supplementary Materials Part 2 and **Supplementary Materials Part 3** show a comparison of AE numbers reported by BKK-ProVita versus those reported by the Paul-Ehrlich-Institut (PEI, comparable to the FDA in the USA). The BKK-ProVita entity is one of the lawful German health insurance companies. Their chairman, Andreas Schöfbeck, summarized data of all AEs (regarding the mRNA vaccines) reported by physicians who treated patients in contract with the BKK-Provita — that is to say, the actual work-flow for physicians to get paid (compensation) after a therapy session or even a diagnosis of a patient. Physicians rate their treatment by the guidelines of the World Health Organization with the help of ICD-10-codes. From the BKK-ProVita data, it follows that between 2.0% and 2.3% of all BKK's insurants (both vaccinated and unvaccinated!) had an AE related to the injection. This is in contrast to the listing of the PEI which documented AEs in merely 0.3% of all cases. As a consequence of having collected these data, presented in **Supplementary Materials Part 2**, Andreas Schöfbeck calculated a scaling for the whole population in Germany (which we have actually repeated in our paper) and wrote a letter (**Supplementary Materials Part 3**) on February 21, 2022 to Klaus Cichutek, the chairman of the PEI, warning him about this "heavy safety signal" ("heftiges Warnsignal"). As a result of this letter, Andreas Schöfbeck was dismissed summarily from his position in the BKK-ProVita management only 8 days later, on March 1, 2022.

Supplementary Materials Part 1

KBV KASSENÄRZTLICHE BUNDESVEREINIGUNG

IMPFSTOFFE GEGEN COVID-19: VERGLEICH ANZAHL DER IMPFUNGEN MIT ANZAHL DER CODIERTEN IMPFNEBENWIRKUNGEN 2016-2021

Anfrage MdB Sichert (AfD) im Gesundheitsausschuss am 21. März 2022

Jahr	Anzahl Impfungen (vertragsärztlicher Bereich)	Anzahl Patienten mit Impfnebenwirkungen* (vertragsärztlicher Bereich)
2016	21.128.611	67.065
2017	21.656.464	68.208
2018	23.213.850	67.789
2019	24.856.747	70.441
2020	29.937.878	76.332

	Anzahl Impfungen gegen Covid-19 (vertragsärztl./nicht-vertragsärztl. Bereich)	Anzahl Patienten mit Impfnebenwirkungen* (vertragsärztlicher Bereich)
2021	153.750.725	2.487.526

* Daten enthalten sowohl übliche und damit nicht meldepflichtige Impfreaktionen als auch meldepflichtige Impfnebenwirkungen

Erläuterungen zur Tabelle:

- Die Anzahl der im vertragsärztlichen Bereich durchgeführten Impfungen für das Jahr 2021 liegen dem Zentralinstitut für die kassenärztliche Versorgung (Zi) noch nicht vollständig vor, so dass dies Daten in der obigen Tabelle nicht dargestellt werden können.
- Für das Jahr 2021 wird die Gesamtzahl der im vertragsärztlichen und nicht-vertragsärztlichen Bereich durchgeführten Impfungen gegen Covid-19 (Quelle: Zi) den im vertragsärztlichen Bereichen codierten Impfnebenwirkungen gegenübergestellt. Nebenwirkungen aufgrund von beispielsweise in einem Impfzentrum oder durch ein mobiles Impfteam durchgeführten Impfungen werden nicht durch diese, sondern i.d.R. durch Vertragsärztinnen und Vertragsärzte behandelt bzw. dokumentiert und gemeldet.
- Zur Erfassung der oben dargestellten Impfnebenwirkungen wurden folgende von Vertragsärztinnen und Vertragsärzten dokumentierte ICD-10-Codes berücksichtigt:
  - U12.9 Unerwünschte Nebenwirkungen bei der Anwendung von COVID-19-Impfstoffen, nicht näher bezeichnet (gültig seit 1. April 2021)
  - Y59.9 Komplikationen durch Impfstoffe oder biologisch aktive Substanzen
  - T88.0 Infektion nach Impfung (inkl. Sepsis)
  - T88.1 Sonstige Komplikationen nach Impfung [Immunisierung], anderenorts nicht klassifiziert (inkl. Hautausschlag nach Impfung)

Bewertung:

Die vom PEI veröffentlichten Daten zu Impfnebenwirkungen weichen von den von Vertragsärztinnen und Vertragsärzten über die o.g. ICD-10-Codes dokumentierten Impfnebenwirkungen aus folgenden Gründen ab:

Nach § 6 Absatz 1 Satz 1 Nummer 3 Infektionsschutzgesetz (IfSG) ist der Verdacht einer über das übliche Ausmaß einer Impfreaktion hinausgehenden gesundheitlichen Schädigung dem PEI zu melden. Diese Meldung gehört zu den ärztlichen Aufgaben.

Zur Abgrenzung einer üblichen Impfreaktion von einer über das übliche Ausmaß einer Impfreaktion hinausgehenden gesundheitlichen Schädigung – die beide über die o.g. ICD-10-Codes dokumentiert werden, von denen aber nur die zweite zu melden ist – hat die STIKO entsprechend § 20 Absatz 2 Satz 3 IfSG Kriterien entwickelt und Merkmale für übliche Impfreaktionen definiert. Übliche und damit nicht meldepflichtige Impfreaktionen sind das übliche Ausmaß nicht überschreitende, vorübergehende Lokal- und Allgemeinreaktionen, die als Ausdruck der Auseinandersetzung des Organismus mit dem Impfstoff anzusehen sind. Die STIKO hat die folgenden Kriterien für übliche Impfreaktionen entwickelt:

- Für die Dauer von 1 bis 3 Tagen (gelegentlich länger) anhaltende Rötung, Schwellung oder Schmerzhaftigkeit an der Injektionsstelle.
- Für die Dauer von 1 bis 3 Tagen Fieber < 39,5°C (bei rektaler Messung), Kopf- und Gliederschmerzen, Mattigkeit, Unwohlsein, Übelkeit, Unruhe, Schwellung der regionären Lymphknoten.
- Im Sinne einer „Impfkrankheit" zu deutende Symptome 1 bis 3 Wochen nach der Verabreichung von attentuierten Lebendimpfstoffen: z.B. eine leichte Parotisschwellung, kurzzeitige Arthralgien oder ein flüchtiges Exanthem nach der Masern-, Mumps-, Röteln- oder Varizellen-Impfung oder milde gastrointestinale Beschwerden, z.B. nach der oralen Rotavirus- oder Typhus-Impfung.
- Ausgenommen von der Meldepflicht sind auch Krankheitserscheinungen, denen offensichtlich eine andere Ursache als die Impfung zugrunde liegt.
- Alle anderen Impfreaktionen sollen gemeldet werden.

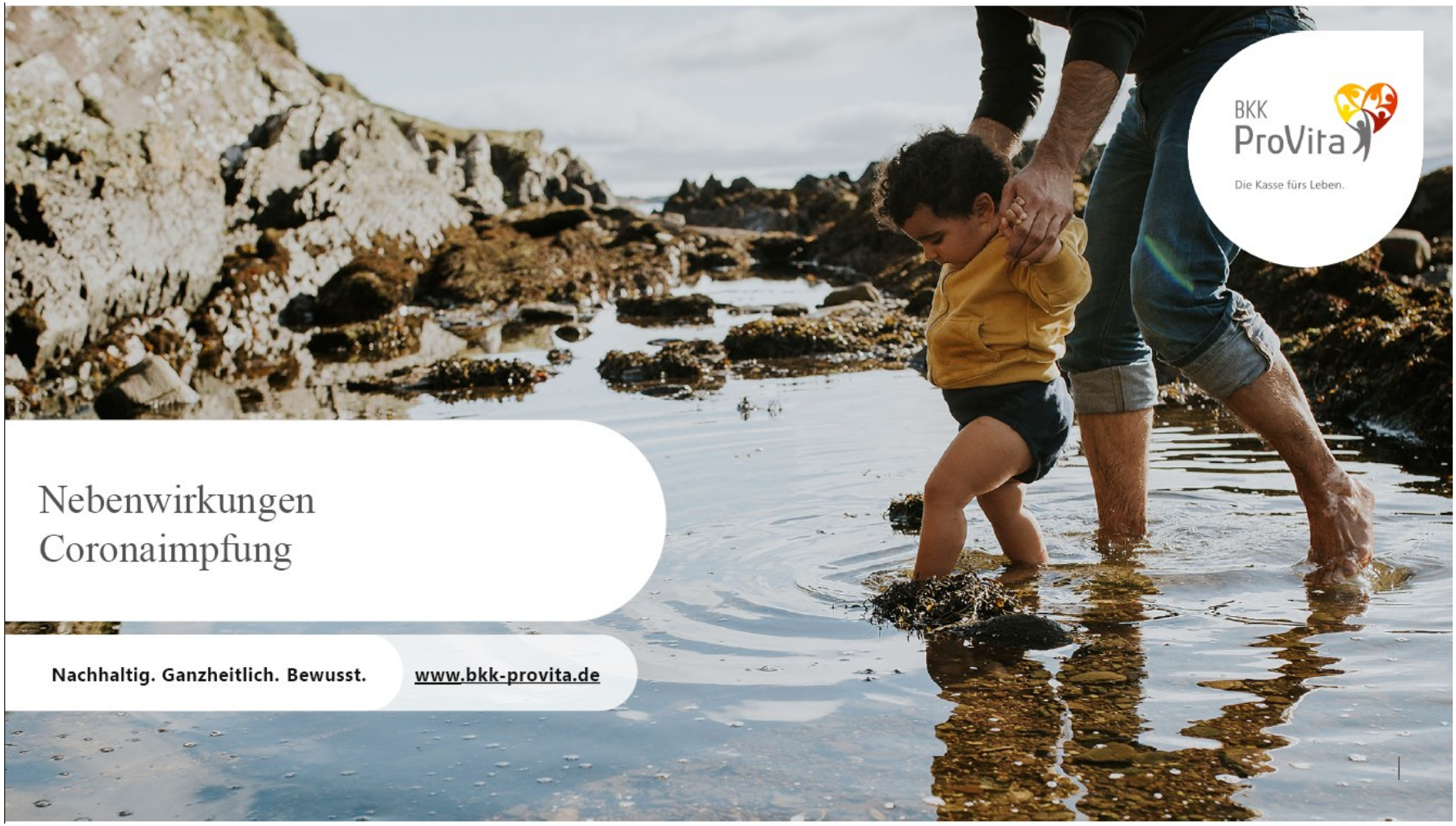
In der Fachinformation von Comirnaty® von BioNTech/Pfizer werden beispielsweise bei den an der Zulassungsstudie teilnehmenden Personen ab 16 Jahren, die 2 Dosen erhielten, als am häufigsten aufgetretene Nebenwirkungen Schmerzen an der Injektionsstelle (> 80 %), Ermüdung (> 60 %), Kopfschmerzen (> 50 %), Myalgie (> 40 %), Schüttelfrost (> 30 %), Arthralgie (> 20) %), Fieber und Schwellung an der Injektionsstelle (> 10 %) genannt, die normalerweise von leichter oder mäßiger Intensität waren und innerhalb weniger Tage nach der Impfung abklangen. Eine etwas geringere Häufigkeit von Reaktogenitätsereignissen war mit einem höheren Alter verbunden. Das Gesamtsicherheitsprofil für die Auffrischungsdosis war ähnlich wie nach 2 Dosen. Die häufigsten Nebenwirkungen bei den Teilnehmern im Alter von 18 bis 55 Jahren waren Schmerzen an der Injektionsstelle (> 80 %), Ermüdung (> 60 %), Kopfschmerzen (> 40 %), Myalgie (> 30 %), Schüttelfrost und Arthralgie (> 20 %).

Die Daten für Spikevax® von Moderna sind beispielsweise bei Personen ab 18 Jahren vergleichbar: Die in der Zulassungsstudie am häufigsten berichteten Nebenwirkungen waren Schmerzen an der Injektionsstelle (92 %), Müdigkeit (70 %), Kopfschmerzen (64,7 %), Myalgie (61,5 %), Arthralgie (46,4 %), Schüttelfrost (45,4 %), Übelkeit/Erbrechen (23 %), Schwellung/Schmerzempfindlichkeit der axillären Lymphknoten (19,8 %), Fieber (15,5 %), Schwellung an der Injektionsstelle (14,7 %) und Rötung (10 %). Die Nebenwirkungen waren für gewöhnlich leicht oder mittelgradig ausgeprägt und bildeten sich innerhalb von wenigen Tagen nach der Impfung zurück. Bei älteren Probanden traten reaktogene Ereignisse etwas weniger häufig auf.

Die oben genannten in den Zulassungsstudien am häufigsten aufgetretenen Impfnebenwirkungen sind i.d.R. den üblichen Impfreaktionen zuzuordnen und werden von Ärztinnen und Ärzten daher nicht an das PEI gemeldet, da sie wie oben ausgeführt nicht meldepflichtig sind. Sie werden jedoch – sofern die Patientinnen und Patienten deswegen in die Arztpraxis kommen bzw. davon berichten und/oder ggf. eine AU-Bescheinigung benötigen – über die entsprechenden ICD-10-Codes patientenbezogen dokumentiert. Der Umfang der patientenbezogenen Dokumentation über den ICD-10-Code im Vergleich zu seit Jahren etablierten Impfstoffen gegen andere Erkrankungen ist den besonderen

Rahmenbedingungen der Covid-19-Impfung bzw. der zur Verfügung stehenden Covid-19-Impfstoffe geschuldet. Bei einer neuen Impfung mit den besonderen Zulassungsgegebenheiten wie bei den Covid-19-Impfstoffen ist mit einer erhöhten Aufmerksamkeit gegenüber Impfreaktionen sowohl bei Patientinnen und Patienten als auch bei Ärztinnen und Ärzten sowie einer verstärkten Motivation, dies anzusprechen bzw. zu dokumentieren, zu rechnen als dies bei jahrelang bekannten Impfungen der Fall ist. Der Unterschied zwischen den von Ärztinnen und Ärzten dokumentierten im Vergleich zu den dem PEI gemeldeten Impfreaktionen ist daher nachvollziehbar und war zu erwarten.

Supplementary Materials Part 2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Codierte Impfnebenwirkungen nach Corona-Impfung

Vergleich Kassendaten zu Werten des Paul-Ehrlich-Institutes

Datenquellen:
InfoNet Stand: 16.02.2022
Filter: ICD: T881, T880, Y599, U129
Diagnosesicherheit: G

Bevölkerung Deutschland:
https://de.statista.com/statistik/daten/studie/2861/umfrage/entwicklung-der-gesamtbevoelkerung-deutschlands/

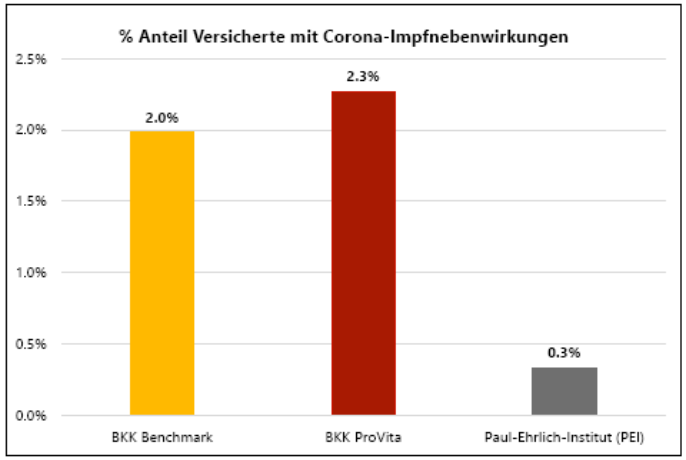
	Jahr	Anzahl V mit ICD T88.0, T88.1, Y59.9 und U12.9	Anzahl CoronaImpfNW	Anzahl sonstige ImpfNW *	% Anteil V CoronaImpfNW an GesamtV
Benchmark	2020	12.264			
	2021	224.360	216.695	7.665	2,0%
BKK ProVita	2020	132			
	2021	2.924	2.842	83	2,3%

Hochrechnung auf Bevölkerung Deutschlands:

	Versicherte
Geamtbevölkerung D	83.200.000
Benchmark	10.937.716
BKK Provita	125.478

Schätzung 2021

	geschätzte V mit CoronaImpfNW	% Anteil V CoronaImpfNW an GesamtV
auf Basis Benchmark	1.648.335	2,0%
auf Basis BKK ProVita	1.884.096	2,3%
Paul-Ehrlich-Institut (PEI)	244.576	0,3%



Kommentar: PEI ganzes Jahr 2021, unsere Daten bilden ca. 2,5 Quartale ab.

* Geschätzte Anzahl Versicherte mit Impfnebenwirkungen bei sonst. Impfungen (Anzahl Jahr 2020 / 4 Quartale * 2,5 Quartale)

Supplementary Materials Part 3

BKK ProVita

Die Kasse fürs Leben.

BKK ProVita - 85217 Bergkirchen

Paul-Ehrlich-Institut
Prof. Dr. Klaus Cichutek
Paul-Ehrlich-Str. 51 - 59
63225 Langen

Es betreut Sie:
Andreas Schöfbeck
Münchner Weg 5
85232 Bergkirchen
T 08131/6133-1000
F 08131/6133-91000
Andreas.Schoefbeck@bkk-provita.de

21.02.2022

Heftiges Warnsignal bei codierten Impfnebenwirkungen nach Corona Impfung

Sehr geehrter Herr Prof. Dr. Cichutek,

das Paul Ehrlich Institut hat mittels Pressemitteilung bekannt gegeben, dass für das Kalenderjahr 2021 244.576 Verdachtsfälle für Impfnebenwirkungen nach Corona Impfung gemeldet wurden.

Die unserem Haus vorliegenden Daten geben uns Grund zu der Annahme, dass es eine sehr erhebliche Untererfassung von Verdachtsfällen für Impfnebenwirkungen nach Corona Impfung gibt. Dazu füge ich meinem Schreiben eine Auswertung bei.

Datengrundlage für unsere Auswertung sind die Abrechnungsdaten der Ärzte. Unsere Stichprobe erfolgt aus dem anonymisierten Datenbestand der Betriebskrankenkassen. Die Stichprobe umfasst 10.937.716 Versicherte. Uns liegen bisher die Abrechnungsdaten der Ärzte für das erste Halbjahr 2021 und circa zur Hälfte für das dritte Quartal 2021 vor. Unsere Abfrage beinhaltet die gültigen ICD-Codes für Impfnebenwirkungen. Diese Auswertung hat ergeben, obwohl uns noch nicht die kompletten Daten für 2021 vorliegen, dass wir anhand der vorliegenden Zahlen jetzt schon von 216.695 behandelten Fällen von Impfnebenwirkungen nach Corona Impfung aus dieser Stichprobe ausgehen. Wenn diese Zahlen auf das Gesamtjahr und auf die Bevölkerung in Deutschland hochgerechnet werden, sind vermutlich 2,5-3 Millionen Menschen in Deutschland wegen Impfnebenwirkungen nach Corona Impfung in ärztlicher Behandlung gewesen.

Das sehen wir als erhebliches Alarmsignal an, das unbedingt beim weiteren Einsatz der Impfstoffe berücksichtigt werden muss. Die Zahlen können in unseren Augen relativ leicht und auch kurzfristig validiert werden, indem die anderen Kassenarten (AOKen, Ersatzkrankenkassen etc.) um eine entsprechende Auswertung der ihnen vorliegenden Daten gebeten werden. Hochgerechnet auf die Anzahl der geimpften Menschen in Deutschland bedeutet dies, dass circa 4-5 % der geimpften Menschen wegen Impfnebenwirkungen in ärztlicher Behandlung waren.

In unseren Augen liegt eine erhebliche Untererfassung der Impfnebenwirkungen vor. Es ist ein wichtiges Anliegen die Ursachen hierfür kurzfristig auszumachen. Unsere erste Vermutung ist, dass, da keine Vergütung für die Meldung von Impfnebenwirkungen bezahlt wird, eine Meldung an das Paul Ehrlich Institut wegen des großen Aufwandes vielfach unterbleibt. Ärzte haben uns berichtet, dass die Meldung eines Impfschadenverdachtsfalls circa eine halbe Stunde Zeit in Anspruch nimmt. Das bedeutet, dass 3 Millionen Verdachtsfälle auf Impfnebenwirkungen circa 1,5 Millionen Arbeitsstunden von Ärztinnen und Ärzten erfordern. Das wäre nahezu die jährliche Arbeitsleistung von 1000 Ärztinnen und Ärzten. Dies sollte ebenso kurzfristig geklärt werden. Deshalb ergeht eine Durchschrift dieses Schreibens auch an die Bundesärztekammer und die Kassenärztliche Bundesvereinigung.

Der GKV-Spitzenverband erhält ebenso eine Abschrift dieses Schreibens mit der Bitte entsprechende Datenanalysen bei sämtlichen Krankenkassen einzuholen.

Da Gefahr für das Leben von Menschen nicht ausgeschlossen werden kann, bitten wir Sie um eine Rückäußerung über die veranlassten Maßnahmen bis 22.2.2022 18:00 Uhr.

Mit freundlichen Grüßen

Andreas Schöfbeck
Vorstand

Das Schreiben ergeht durchschriftlich ebenso an:
GKV-Spitzenverband
Bundesärztekammer
Kassenärztliche Bundesvereinigung
Ständige Impfkommission
BKK Dachverband

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