Evaluation of the publication Kuhbandner and Reitzner 2023 on excess mortality and increased number of stillbirths in Germany in the period from 2020 to 2022:

Is there a causal relationship between mRNA vaccination and high excess mortality as well as with an increase in stillbirths in **2021 and 2022 in Germany?**

Underlying Publication

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Estimation of Excess Mortality in Germany During 2020-2022

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Remarks

The following discussions consist for the most part of translations of passages from the underlying publication and an adaptation of previously unpublished remarks by the author Prof. Kuhbandner. In order to connect the different parts in a meaningful way, wording has been adapted and content added.

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Abstract

Background

The study by Kuhbandner and Reitzner (2023) estimates the burden of COVID-19 on mortality in Germany. It is assumed that many people died due to COVID-19 who would not have died otherwise. Estimating the burden of mortality from the COVID-19 pandemic using the number of officially reported COVID-19-related deaths has proven difficult for several reasons. A better approach, which has been used in many studies, is therefore to estimate the burden of the COVID-19 pandemic by calculating excess mortality in the pandemic years. One advantage of such an approach is that it also captures additional negative effects of a pandemic on mortality, such as a possible pandemic-related burden on the health system.

Methods

In order to calculate excess mortality in Germany for the pandemic years 2020 to 2022, this study compares the reported number of total deaths (i.e. the number of deaths regardless of the underlying causes) with the number of statistically expected total deaths. To do this, the most modern method of actuarial science, based on population tables, mortality tables and longevity trends, is used to estimate the expected number of deaths in 2020 to 2022 in the absence of a pandemic.

Results

The results show that the observed number of deaths in 2020 was close to the expected number in terms of the empirical standard deviation; approximately 4,000 excess number of deaths occurred. In contrast, the observed number of deaths in 2021 was two empirical standard deviations above the expected number and in 2022 even more than four times the empirical standard deviation. Overall, the number of excess deaths is about 34,000 in 2021 and about 66,000 deaths in 2022, giving a cumulative number of 100,000 excess deaths in both years. The high excess mortality in 2021 and 2022 is mainly due to an increase in deaths in the 15-79 age groups and only started to accumulate from April 2021. A similar mortality pattern was observed for stillbirths, which increased by 9.4% in the second quarter of 2021 and 19.4% in the fourth quarter of 2021 compared to previous years.

Conclusions

The results of the present study indicate that an event must have taken place in spring 2021 that led to a sudden and sustained increase in mortality in Germany, although no such effects on mortality had previously been observed during the early COVID 19 pandemic (2020). Due to the extent of the excess mortality and increase in stillbirths observable from spring 2021 onwards, the cause must lie in an event that

- 1. affected a large part of the total population and
- 2. was capable of causing fatal consequences.

Corresponding analyses suggest that the sought event can probably only have been the use of the novel COVID-19 vaccines. After the vector vaccines were no longer or hardly ever administered* due to thrombotic side effects as early as mid-2021, only the mRNA vaccines remain as a probable cause for both the excess mortality found and the increase in stillbirths.

^{*} Bundesministerium fuer Gesundheit, impfdashboard.de, as of 08 April 2023

Possibilities and limitations of the present statistical analyses

From a perspective of pharmacovigilance (drug safety surveillance), the co-occurrence of excess mortality and vaccination constitutes a so-called safety signal. Safety signals, such as the observation of a temporal relationship between vaccine administration and the occurrence of adverse events, do not necessarily imply a causal relationship, as there may be potential third variables that influence both the course of vaccination and the course of excess mortality. Hence, a safety signal here does not necessarily imply that there is a causal relationship between the adverse event and the drug, either; it merely substantiates a hypothesis that requires further evaluation.

After an excess mortality correlating with the administration of mRNA vaccines was proven in the publication on which this is based using the strict and most modern methods of actuarial mathematics, the question arises as to what the Paul-Ehrlich-Institut (PEI), the authority responsible for the safety monitoring of vaccines in Germany, found in this regard. However, the result of a corresponding search yielded no indication that the PEI had also identified the signal found by Kuhbandner and Reitzner of an excess mortality correlating with vaccination in Germany*.

A closer examination of the methods used by the PEI to monitor vaccination side effects, including possible fatal side effects of COVID-19 vaccinations, shows why this is inevitably the case**: The so-called "observed-versus-expected" analysis used by the PEI compares the frequency of a reported adverse reaction with the so-called background incidence, i.e. the frequency of an adverse reaction in the general population. If the frequency in the group of vaccinated persons exceeds the expected frequency based on the data on the general population, this is considered a safety signal. The latter means that the number of reported suspected cases is compared with a frequency occurring in the general population. However, if deaths after vaccination are reported as suspected cases of vaccine causation, these would have to be matched with the incidence of all deaths in the general population. This is such a high number, however (including all deaths from all cancers, cardiac and respiratory diseases), that even a very distinct clustering of post-vaccination deaths would not be detectable.

This shortcoming of the methodology used by the PEI makes it impossible to arrive at a serious result if the aim is to test for the presence of a safety signal "correlation with excess mortality". It is therefore not surprising that the PEI missed the safety signal of excess mortality in correlation with COVID-19 vaccination identified by Kuhbandner and Reitzner.

Now that the safety signal "High general excess mortality and increased rate of stillbirths after mRNA vaccination" has been identified by Kuhbandner and Reitzner, it is important to evaluate this signal in the literature comparison with regard to possible causes for a causal relationship.

* Main source Paul-Ehrlich-Institut:

Report on suspected cases of adverse reactions and vaccination complications after vaccination to protect against COVID-19. Reporting period 27.12. 20 - 31.10.22 (December 2022).

https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/sicherheits berichte/sicherheitsbericht-27-12-20-bis-31-10-22-aus-bulletin-zur-arzneimittelsicherheit-4-2022-s-29-34.pdf?__blob=publicationFile&v=4

** Paul-Ehrlich-Institut: FAQ - Effectiveness and safety

https://www.pei.de/DE/service/faq/coronavirus/faq-coronavirus-node.html?cms_activeFAQ= 423854&cms_tabcounter=2#anchor_423854

Evaluation of the safety signal "High overall excess mortality and increased rate of stillbirths after mRNA vaccination".

The evaluation of safety signals is a multifactorial approach that relates the obtained data to the totality of available research results. In this context, it is particularly important to arrive at a valid general overview from the temporal correlations of the signal by comparing them with literature evidence for causal findings, which condenses statistical correlations into causal relationships with sufficient probability.

For a general excess mortality or an increased rate of stillbirths, which were ultimately calculated from demographic data, it is extremely difficult to prove specific causalities due to the variety of possible causes. However, this would also not be directly useful, since the causality of death is of a highly complex multifactorial nature. In the case of the safety signal of excess mortality after mRNA vaccination identified by Kuhbandner and Reitzner, however, there is the extremely rare constellation that a high excess mortality correlates with a potential cause that affects a very large number of people in the statistical population (in this case, the German population). This otherwise only applies to disaster scenarios such as radioactive, chemical or biological contamination, floods or earthquakes that affect larger areas.

Due to the existence of corresponding conditions, it was possible for a team of pathologists from Heidelberg University Hospital, led by Prof. Schirmacher*, to develop a meaningful study scenario. For this purpose, 35 deceased persons were autopsied whose death occurred within 20 days after COVID-19 vaccination and who were found dead at home with an unclear cause of death. The results of the autopsies were evaluated with regard to a possible causality of the vaccination for the cause of death. In only 10 cases could causes of death due to pre-existing conditions be established. In three cases, it was concluded from the autopsies that vaccine-induced myocarditis was the likely cause of death, and in a further two cases, vaccine-induced myocarditis was possibly the cause of death. Of these five cases, three occurred after the first and one after the second vaccination with BioNTech's mRNA vaccine, and another case involved a person after their first vaccination with Moderna's mRNA vaccine.

This result is highly alarming. After all, it shows that there is a high probability that the excess mortality in Germany calculated by Kuhbandner and Reitzner is not only correlated with mRNA vaccinations, but is also causally linked. This finding is also confirmed in other scientific publications, with the number of corresponding studies steadily increasing. This is particularly worrying because preclinical safety studies were not carried out during the development of mRNA vaccines, even after their conditional approval.

^{*} Schwab C, Domke LM, Hartmann L, Stenzinger A, Longerich T, Schirmacher P: Autopsy-based histopathological characterization of myocarditis after anti-SARS-CoV-2-vaccination. Clin Res Cardiol. 2023, 112:431-40. 10.1007/s00392-022-02129-5

Overview of essential statistical evidence of the underlying publication in relation to excess mortality and stillbirths 2020 to 2022 (adaptation of previously unpublished comments by the author Prof. Kuhbandner).

Yearly observation

From an annual perspective, there was no noticeable excess mortality in 2020; the number of unexpected deaths is within the usual range of variation. In 2021, with 34,000 more deaths than statistically expected, there is a clear excess mortality that is two standard deviations above the expected value. In 2022, with 66,000 more deaths than expected, there is extreme excess mortality that is more than four standard deviations above the expected value.

So while there was no noticeable excess mortality in 2020 - the year the pandemic began - in 2021 and 2022 combined, about 100,000 more people died than is normally the case. The excess mortality in 2021 and 2022 is found especially in the younger age groups. In 2022, 10.5 percent more people than expected died in the 15-29 age group and 9.7 percent more than expected in the 30-39 age group.

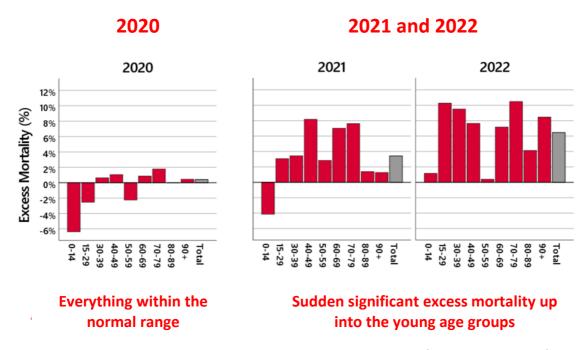


Figure 1 of the publication Kuhbandner and Reitzner 2023 (comments added): Excess mortality in Germany by age group 2020 to 2022

Monthly observation

A month-by-month observation shows that there was an excess mortality at the turn of the year 2020/2021, which was age-dependent and affected the older age groups in particular, and which was partly offset by a subsequent under-mortality in the following months of February and March. These were therefore mainly anticipatory effects, which led to vulnerable persons who would normally have died in February and March dying somewhat earlier. From April 2021 - the start of the vaccination campaign - this pattern changes fundamentally: suddenly there is an excess mortality up to the youngest age groups, which is no longer compensated by subsequent phases of undermortality, but instead becomes increasingly stronger. A closer look further shows that the younger the age group, the later the excess mortality appears, which corresponds to the time course of vaccinations.

Age-dependent excess mortality, offset by subsequent periods of undermortality Excess mortality up to the youngest age groups, peak occurs later as the age group gets younger

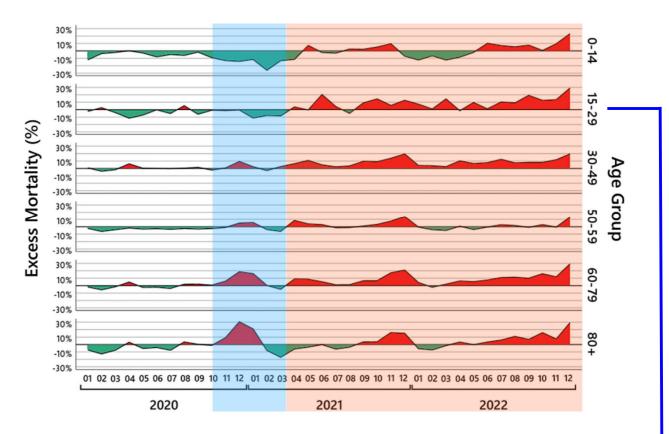
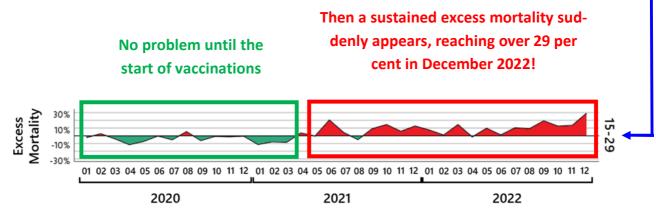


Figure 4 of the publication Kuhbandner and Reitzner 2023 (modified and extended): Excess mortality in Germany 2020 to 2022 by age group over time

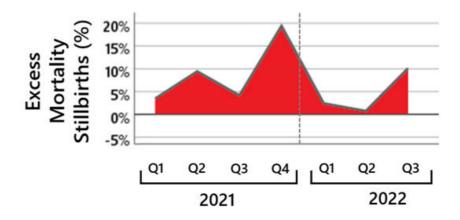
In the age group 15-29, which was practically unaffected by COVID-19, one sees the striking progression of excess mortality over time as if in a burning lens:



Extract from Figure 4 of the publication Kuhbandner and Reitzner 2023 (modified and extended): Excess mortality in Germany 2020 to 2022 of the age group 15 to 29 over time

Stillbirths

The increase in stillbirths during the period in question is probably examined for the first time in Kuhbandner and Reitzner 2023. There, too, a distressing pattern emerges. Compared to previous years, the rate of stillbirths per total number of all births shows an increase of 9.4 per cent in the second quarter of 2021 and an increase of 19.4 per cent in the fourth quarter, which corresponds to an increase of four standard deviations compared to the range of variation in previous years. This pattern of increase - an initial smaller increase in the second quarter and a larger increase in the fourth quarter of 2021 - coincides with public recommendations for vaccination during pregnancy. Already in the second quarter of 2021, German gynaecological societies recommended COVID vaccination for all pregnant women, although STIKO had not yet issued such a recommendation*. Then, in mid-September 2021 - i.e. shortly before the start of the fourth quarter - the STIKO explicitly recommended vaccination for all previously unvaccinated or incompletely vaccinated pregnant women from the 2nd trimester of pregnancy onwards. It is worrying that the stillbirth rate is also significantly increased in 2022.



Extract from Figure 6 of the publication Kuhbandner and Reitzner 2023: Excess mortality in the form of miscarriages in Germany in 2021 and 2022 over time

Temporal association between COVID-19 deaths and COVID-19 vaccinations

The discussion of the publication Kuhbindner and Reitzner 2023 also looks at the temporal relationships between COVID-19 deaths and COVID-19 vaccinations. With regard to COVID-19 deaths, it is shown that the excess mortality since the beginning of the vaccination campaign cannot be explained by the course of COVID deaths. From February 2021 onwards, the excess mortality curve becomes decoupled from the curve of COVID-19 deaths. Despite a period of significant undermortality, a high number of COVID-19 deaths (so-called "corona deaths") continued to be reported, which casts great doubt on the validity of the diagnosis "COVID-19 death". Apparently, this diagnosis was also frequently used for deaths of people who died independently of COVID-19, i.e. "with COVID-19" instead of "from COVID-19". As of September 2021, excess mortality was higher than the number of COVID deaths, and in 2022 excess mortality ultimately exploded, while the number of COVID-19 deaths increasingly declined.

^{*} Pharmazeutische Zeitung of 03 May 2021:
Covid-19 vaccination recommendation for all pregnant women
https://www.pharmazeutische-zeitung.de/covid-19-impfempfehlung-fuer-alle-schwangeren-125392/

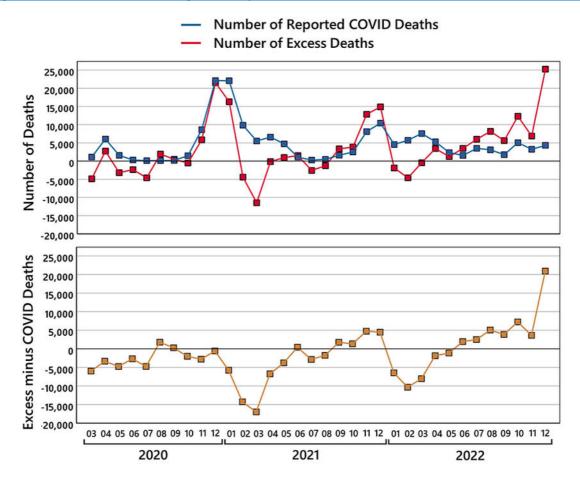


Figure 7 of the publication Kuhbandner and Reitzner 2023:
Course of excess mortality and deaths "with COVID-19" in Germany 2020 to 2022

When looking at the temporal relationship with vaccinations, a completely different picture emerges. If one looks at the cumulative course of the number of unexpected deaths (excess mortality) and the COVID-19 vaccinations together, a different picture emerges:

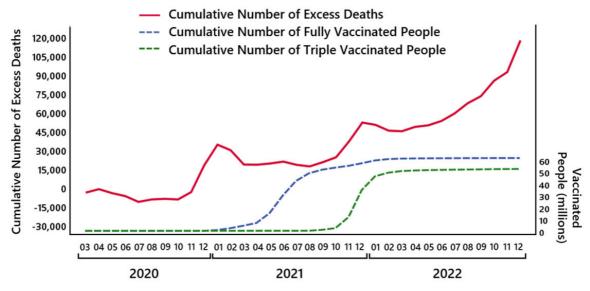


Figure 8 of the publication Kuhbandner and Reitzner 2023:
Course of excess mortality and vaccination against COVID-19 in Germany 2020 to 2022

Despite the fact that a large part of the population particularly affected by the severity of COVID-19 was vaccinated twice or three times, there is no relevant effect in terms of a decrease in excess mortality. Instead, the excess mortality in 2022 even increases significantly more than in the previous years. A closer look at the temporal course of vaccinations and excess mortality per month reveals the following picture:

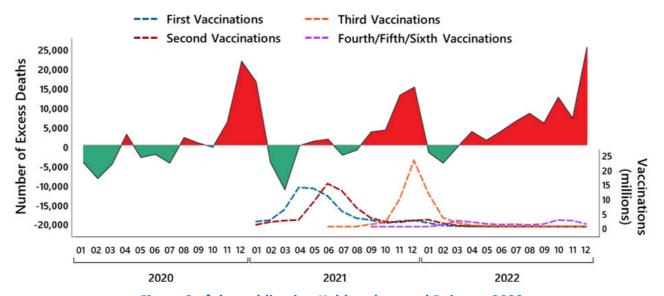


Figure 9 of the publication Kuhbandner and Reitzner 2023:

Course of excess mortality compared with the course of the number of vaccinations of individuals against COVID-19 in Germany 2020 to 2022.

This graph alone makes the claim that vaccinations have prevented a great number of deaths appear highly questionable. Rather, one gets the opposite impression, especially with regard to the long-term effects.

The temporal correlation between the course of vaccination and excess mortality is particularly pronounced for the third vaccination. In September and October 2021, the initially small increase in the number of third vaccinations was accompanied by a comparatively small increase in excess deaths. In November and December 2021, the number of third vaccinations increased sharply, which was accompanied by a comparatively large increase in unexpected deaths. In January 2022, the number of the third vaccination declined sharply, which in turn was accompanied by a comparatively strong decline in excess deaths.

Conclusion

Even if correlation does not automatically mean causality, the correlations found by Kuhbandner and Reitzner would correspond exactly to the pattern that would be expected if the vaccination of mRNA vaccines causally led to deaths. This means nothing less than the presence of a safety signal with a previously unimaginable dimension in terms of the number of deaths.

Accordingly, there is an urgent need for action on the part of the competent authorities and the companies that market mRNA vaccines, in accordance with the legal regulations provided for such a scenario. This means that it must be investigated and evaluated as soon as possible whether the correlation between mRNA vaccinations and excess mortality shown by Kuhbandner and Reitzner (2023) using the most modern statistical methods is causally linked, i.e. whether excess mortality and the increase in the rate of stillbirths can be confirmed or ruled out as consequences of mRNA vaccinations.