

Effectiveness of the BNT162b2 (COMIRNATY) vaccination in protecting from death due to COVID-19 in Poland: epidemiologic commentary and limitations

To the editor Thank you for publishing a very important article by Pietrzak et al¹ that, using accessible language and methodology, shows medical practitioners, who are not specialists in the analysis of biomedical data, the effectiveness of a specific vaccine in protecting against COVID-19-associated deaths in Poland. The authors adopted several simplifications, which can be justified, as the work is addressed to a wide audience. However, the data need a deeper interpretation on the part of a professional reader (eg, if the paper is discussed in the context of a specialist journal or conference). The analysis requires a commentary from an epidemiologic point of view, as it may be misinterpreted by people who are not educated in the field of epidemiology. As there are several possible limitations (ie, related to data availability and study type—retrospective, nonanalytical, observational), and we know that vaccination and deaths from COVID-19 in Poland are significantly moderated by multiple factors, such as health care access,² I have only highlighted factors within the authors' control.

Firstly, the authors state that this is the first study on the effectiveness of vaccination in mitigating death due to COVID-19 in Poland. It is probably the first for the BNT162b2 (COMIRNATY) vaccine, but in general, the relationship between vaccinations and deaths has been studied by multiple institutions and independent researchers. I will mention here just the studies published in scientific journals and series, such as the first version of the National Institute of Public Health-National Institute of Hygiene (NIZP-PZH) report,³ with serious shortcomings (see discussion <http://interdisciplinary-research.eu/aotmit-bledy-w-zalaceniach>), such as incorrectly calculated youths' exposure time (at least 2-fold) or incorrect classification of vaccination status (for over 3 million patients), as well as the second revised version of this report. Moreover, there is a study (methodologically similar to that by Pietrzak et al¹) by the European Centre for Disease

Prevention and Control with a Polish chapter covering only the senior population.⁴

Secondly, the authors claim that data on adverse events (AEs; the term "side effects" is originally used in the paper) are unavailable. The fact is that the data on AEs in Poland are scarce. However, the State Sanitary Inspection and later the NIZP-PZH have indicated 6 probable deaths associated with the BNT162b2 (COMIRNATY) vaccination up to December 31, 2022 based on a causal analysis.⁵ When calculating vaccine effectiveness (VE), it is also worth making a correction for the harm-benefit analysis (which does not change the picture much due to the low prevalence of lethal AEs).

Thirdly, the authors adopted a simplified study scheme that does not take into account the time of exposure to infection and its effect in the form of death. Consequently, they potentially overestimated the protective effectiveness of the vaccination, because unvaccinated people, as a rule, have a longer exposure time than the vaccinated ones, for whom the protective effect could appear somewhere during the analyzed period (eg, after taking the second dose of the BNT162b2 [COMIRNATY] vaccine). There are multiple analytical epidemiologic tools to adjust for that.

Fourthly, the authors did not discuss why the protective effect of the vaccination remains at a high level practically throughout the entire observation period, despite reports indicating a greater decrease in the protective effect against death in other analyses of this type (eg, for the United States, <https://data.cdc.gov/Public-Health-Surveillance/Rates-of-COVID-19-Cases-or-Deaths-by-Age-Group-and/3rge-nu2a/data> VE dropped from 95% in late 2021 to 90% in early 2022, and below 80% in mid-2022). This may raise an objection that the authors deliberately terminated the analysis at the beginning of January 2022 (and the value of the work is historical only with limited clinical application right now), when the wave of the Omicron group of variants,

for which vaccination-induced immunity was declining, was just beginning in Poland.

Finally, the authors adopted a binary classification of fully vaccinated/unvaccinated, disregarding the complexity of the booster effect. The positive effect of the booster for fall of 2021 can be seen in Table 4, because in the authors' simplification, subsequent doses are not included, although a significant percentage of fully vaccinated people received the booster dose then. Interpreting the other figures or results would be easier if connections were made to the other epidemiologic facts not stated.

In conclusion, the article is an accessible study for doctors and other medical professionals. My comments are not accusations but only remarks indicating the consequences of the assumptions made. However, some conclusions, such as the number of avoidable deaths due to low vaccination coverage in Poland (journalists would probably come up with the number of 60 000 lives lost), should be provided with an epidemiologic commentary on the factors depending on the authors, such as calculating exposure time, identifying successive waves, the effect of boosters or AEs, as well as the limitations of a retrospective observational study regarding general or data quality issues, so that they do not provide the opponents of segregation due to vaccination with reliable arguments.

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CONFLICT OF INTEREST None declared.

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