

# Effectiveness of the BNT162b2 vaccine in preventing COVID-19–associated deaths in Poland

Łukasz Pietrzak<sup>1</sup>, Kamil Polok<sup>2,3</sup>, Rafał Halik<sup>4</sup>, Agnieszka Szuster-Ciesielska<sup>5</sup>, Wojciech Szczeklik<sup>2</sup>

<sup>1</sup> Mazovian Pharmaceutical Chamber, Warsaw, Poland

<sup>2</sup> Center for Intensive Care and Perioperative Medicine, Jagiellonian University Medical College, Kraków, Poland

<sup>3</sup> Department of Pulmonology, Jagiellonian University Medical College, Kraków, Poland

<sup>4</sup> Department of Population Health Monitoring and Analysis, National Institute of Public Health NIH – National Research Institute, Warsaw, Poland

<sup>5</sup> Department of Virology and Immunology, Institute of Biological Sciences, Maria Curie-Skłodowska University, Lublin, Poland

## KEY WORDS

COVID-19, COVID-19 epidemiology, COVID-19 vaccines

## ABSTRACT

**INTRODUCTION** Development of vaccines was a turning point of the COVID-19 pandemic. In this study, we describe the course of the vaccination program in Poland and the effectiveness of the BNT162b2 vaccine.

**OBJECTIVES** The aim of the study was to analyze the vaccination rates and effectiveness stratified by age groups in Poland.

**PATIENTS AND METHODS** This is a retrospective study based on the data on the vaccination rate and survival status among Polish citizens, obtained from the registries kept by the Polish Ministry of Health, the Statistics Poland, and the European Centre for Disease Prevention and Control. The data were collected between week 53 of 2020 and week 3 of 2022. The final analysis included patients who were either not vaccinated at all or fully vaccinated with the BNT162b2 vaccine.

**RESULTS** The database contained records of 36 362 777 individuals, of whom 14 441 506 (39.71%) were fully vaccinated with the BNT162b2 vaccine and 14 220 548 (39.11%) were not vaccinated at all. The weekly average effectiveness of the BNT162b2 vaccine in preventing death was 92.62% and varied from 89.08% for the citizens aged 80 years and older, to 100% for individuals aged 5 to 17 years. The estimated mortality rate was significantly higher in the unvaccinated group than in the fully vaccinated group in the entire cohort (447.9 per 100 000 vs 43.76 per 100 000;  $P < 0.001$ ) in all age categories.

**CONCLUSIONS** The study results confirm high effectiveness of the BNT162b2 vaccine in preventing COVID-19 deaths in all analyzed age groups.

**INTRODUCTION** Vaccines are deemed one of the most valuable and effective tools in the prevention of infectious diseases and their sequelae, including disability and death. The World Health Organization (WHO) estimates that each year vaccinations prevent from 3.5 to 5 million deaths globally.<sup>1</sup> Vaccines are not only a tool applied to maintain health and well-being of the population, but they are also an effective measure used in tackling disease outbreaks.

One of the most spectacular examples of vaccine importance is the COVID-19 pandemic. The development of messenger RNA (mRNA)

vaccines against COVID-19 provided health care systems with new measures to combat the pandemic on a global scale. Clinical trials have shown extraordinary performance of these vaccines against symptomatic COVID-19, reaching 95% for the BNT162b2 and 94.1% for the mRNA-1273 vaccine<sup>2,3</sup> at an early stage of the pandemic. Altogether, the introduction of universal vaccinations significantly changed the course of the pandemic, and could have prevented approximately 14.4 million of COVID-19–associated deaths worldwide between December 2020 and the end of 2021.<sup>4</sup>

Correspondence to:  
Wojciech Szczeklik, MD, PhD,  
Jagiellonian University Medical  
College, Center for Intensive  
Care and Perioperative Medicine,  
ul. Wrocławska 1–3, 30-901 Kraków,  
Poland, phone: +48 12 630 82 67,  
email: wojciech.szczeklik@uj.edu.pl  
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## WHAT'S NEW?

This is the first report on the course of the vaccination program in Poland. It comprehensively describes the vaccination rate and effectiveness of the BNT162b2 vaccine in preventing COVID-19–associated deaths. Its main strength is the inclusion of all Polish citizens and the use of publicly available information from governmental databases. Such an approach ensures validity of our analysis and allows for drawing valuable conclusions for further research and management of the ongoing vaccination program.

So far, there have not been any available reports on the performance of the vaccination program in Poland. Therefore, we used the publicly available databases to evaluate the rate and effectiveness of the BNT162b2 vaccine in the Polish population, including stratification by age groups. To paint a more complete picture, we investigated temporal trends in the number of fully vaccinated individuals, and estimated mortality in the fully vaccinated and unvaccinated people.

**PATIENTS AND METHODS** **Study design and setting** This is a retrospective study based on the anonymized data on vaccination and survival status among the Polish citizens, provided by the Polish Ministry of Health, the Statistics Poland (a governmental office responsible for collecting and publishing statistical data on the national level), and the European Centre for Disease Prevention and Control (ECDC).<sup>5,6</sup> The data were collected between week 53 of 2020 and week 3 of 2022. Overall, there were 76 733 deaths registered among patients diagnosed with COVID-19 in all age groups in the analyzed period. The age structure for the Polish population was assessed as of December 31, 2020.

**Study population** The final analysis included patients who were either not vaccinated at all or fully vaccinated with the BNT162b2 vaccine. The patients who were only partially vaccinated (received 1 dose of the BNT162b2 vaccine) or were vaccinated with a vaccine different than BNT162b2 (ie, ChAdOx1, Ad26.COV2.S, or mRNA-1273) were excluded from the final analysis concerning the vaccine efficiency. The study flowchart is presented in [FIGURE 1](#).

**Data sources, definitions, and study groups** The available information about patients who died included their date of death, sex, age, vaccination status, and for those who were vaccinated also the type of the vaccine, number of administered doses, and exact dates of vaccination. The study database also included weekly reported data on the vaccination status stratified by age (provided by ECDC) and data on the general population of Poland stratified by age (provided by the Statistics Poland). The patients were divided into fully vaccinated and not vaccinated groups. The individuals were considered fully vaccinated 2 weeks after administration of the second dose of

a 2-dose vaccine, or 2 weeks after administration of a single-dose vaccine. In each group, the data were further divided according to age (5–9, 10–17, 18–24, 25–49, 50–59, 60–69, 70–79, ≥80 years), week of the year, and the time from full vaccination to death.

### Timeline of the vaccination program in Poland

The COVID-19 vaccination program in Poland began on December 27, 2020. Initially, the vaccines were available for medical professionals employed in hospitals, outpatient clinics, long-term care facilities and pharmacies, hospital administrative employees, medical students, and individuals employed at medical universities. On January 15, 2021, registration for the vaccination began for patients aged at least 80 years in the general population. Since then, the vaccinations became gradually available for younger Polish citizens until May 10, 2021, when the registration was opened to all adult Poles. Moreover, in February 2021 all teachers and people employed in the educational sector were included in the vaccination program, and in March 2021 the registration was opened to patients with selected chronic diseases (chronic renal failure requiring dialysis, chronic respiratory failure requiring long-term mechanical ventilation, cancer and recent chemo- or radiotherapy, history of organ, tissue, or cell transplant).

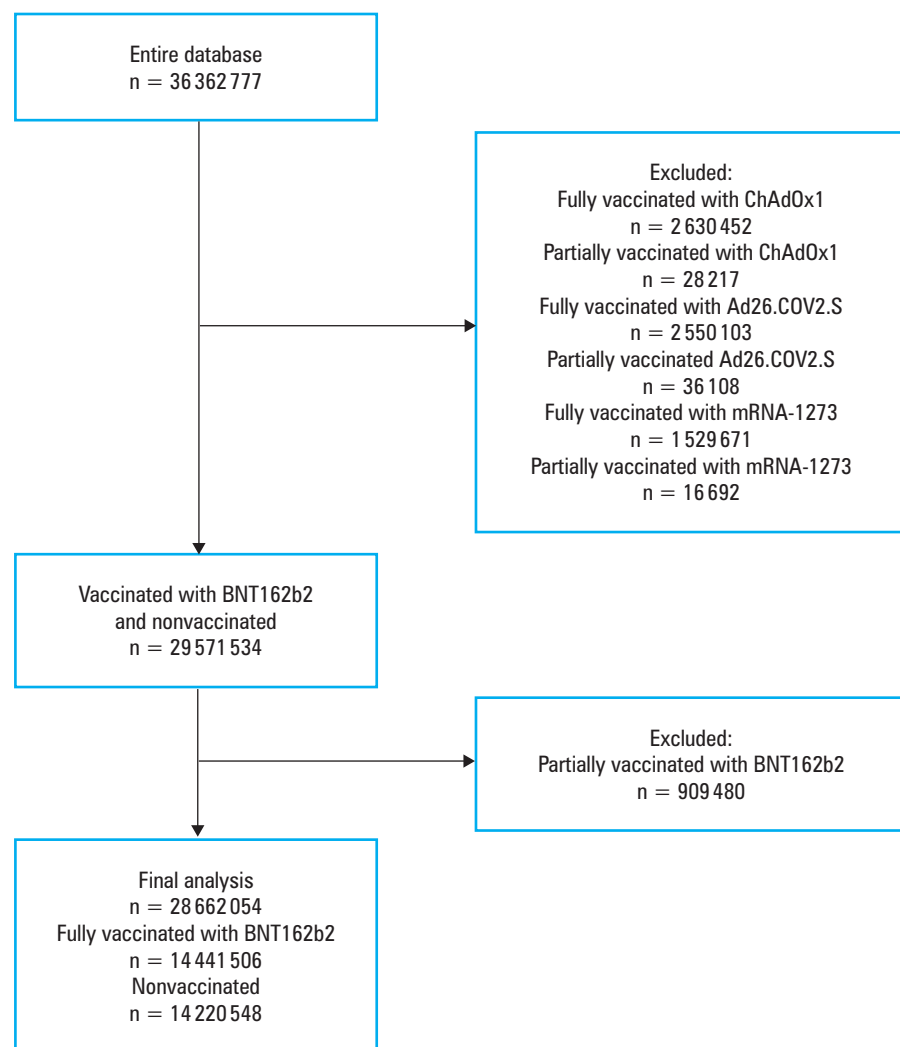
**Statistical analysis** Categorical variables were presented as numbers (percentage), while continuous variables were presented as means (SD). Differences in mortality between the groups were evaluated using the  $\chi^2$  test or the Fischer exact test, as appropriate.

The risk of primary outcome, that is, COVID-19–associated death, was determined separately for each week, and stratified by the study group and the abovementioned age categories. The risk of death was measured as the mortality rate, that is, we divided the number of people who died due to COVID-19 by the number of people in a given study group and age category in the analyzed week.

Vaccine effectiveness (VE) was measured by calculating the risk of death, and determining the percentage reduction in death risk among the vaccinated and unvaccinated individuals. The greater the percentage reduction of deaths in the vaccinated group, the greater the VE. The basic formula is as follows:

$$VE = (\text{risk in the unvaccinated group} - \text{risk in the vaccinated group} / \text{risk in the unvaccinated group}) \times 100\%.$$

Additionally, we analyzed the time of death in relation to the BNT162b2 vaccination time. Finally, the number of potentially avoidable deaths was estimated by subtracting the number of deaths that would have occurred in the nonvaccinated group if the mortality rate was equal to the mortality rate in the vaccinated group from the actual number of deaths in the nonvaccinated group.



**FIGURE 1** Study flow chart

All statistical analyses were conducted using Microsoft Excel 2022 (Microsoft, Redmond, Washington, United States) and R Studio (R Foundation for Statistical Computing, Vienna, Austria).

### RESULTS Study sample and vaccination status

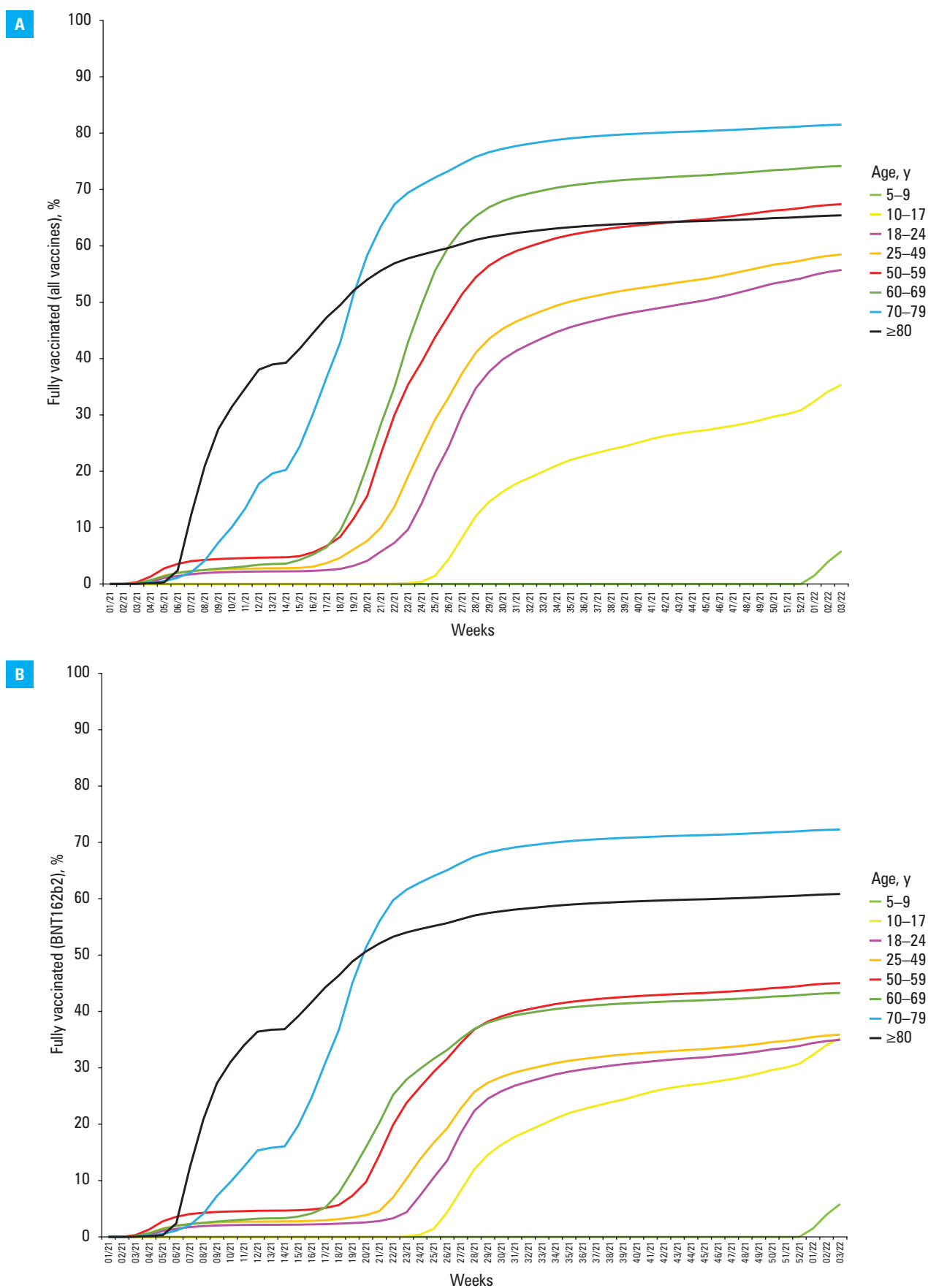
The entire database contained 36 362 777 individuals, of whom 21 151 732 (58.17%) were fully vaccinated. The study participants received full vaccination with the BNT162b2 (14 441 506, 68.28%), ChAdOx1 (2 630 452, 12.44%), Ad26.COV2.S (2 550 103, 12.05%), or mRNA-1273 (1 529 671, 7.23%) vaccine. **FIGURE 2A** and **2B** presents temporal trends in the vaccination status for all vaccines and the BNT162b2 vaccine, respectively. **FIGURE 3** presents the proportion of vaccines administered throughout the study period in weekly intervals.

**Vaccine effectiveness** Over the entire study period, the BNT162b2 vaccine achieved an average weekly effectiveness of 92.62% in preventing COVID-19–associated deaths. The value varied from 89.1% in the individuals aged 80 years and

older to 100% in the individuals aged 5 to 17 years. **TABLE 1** summarizes the total BNT162b2 VE stratified by the age groups. **FIGURE 4** depicts the 4-week average effectiveness of the BNT162b2 vaccine stratified by the age groups.

**COVID-19 mortality and vaccination status** There were 6643 deaths due to COVID-19 in all age groups of people vaccinated with the BNT162b2 vaccine. The mean age at the time of death was 78.64 (10.17) years. The group of nonsurvivors included 2854 women (mean age, 79.8 [10.19] years) and 3789 men (mean age, 77.7 [10.06] years). Among the unvaccinated people, there were 64812 deaths resulting from COVID-19 (mean age, 75 [12.6] years), including 30 577 women at the mean age of 77.7 (12.11) years, 34 073 men at the mean age of 72.7 (12.53) years, and 162 patients of undetermined sex at the mean age of 69.5 (17.51) years.

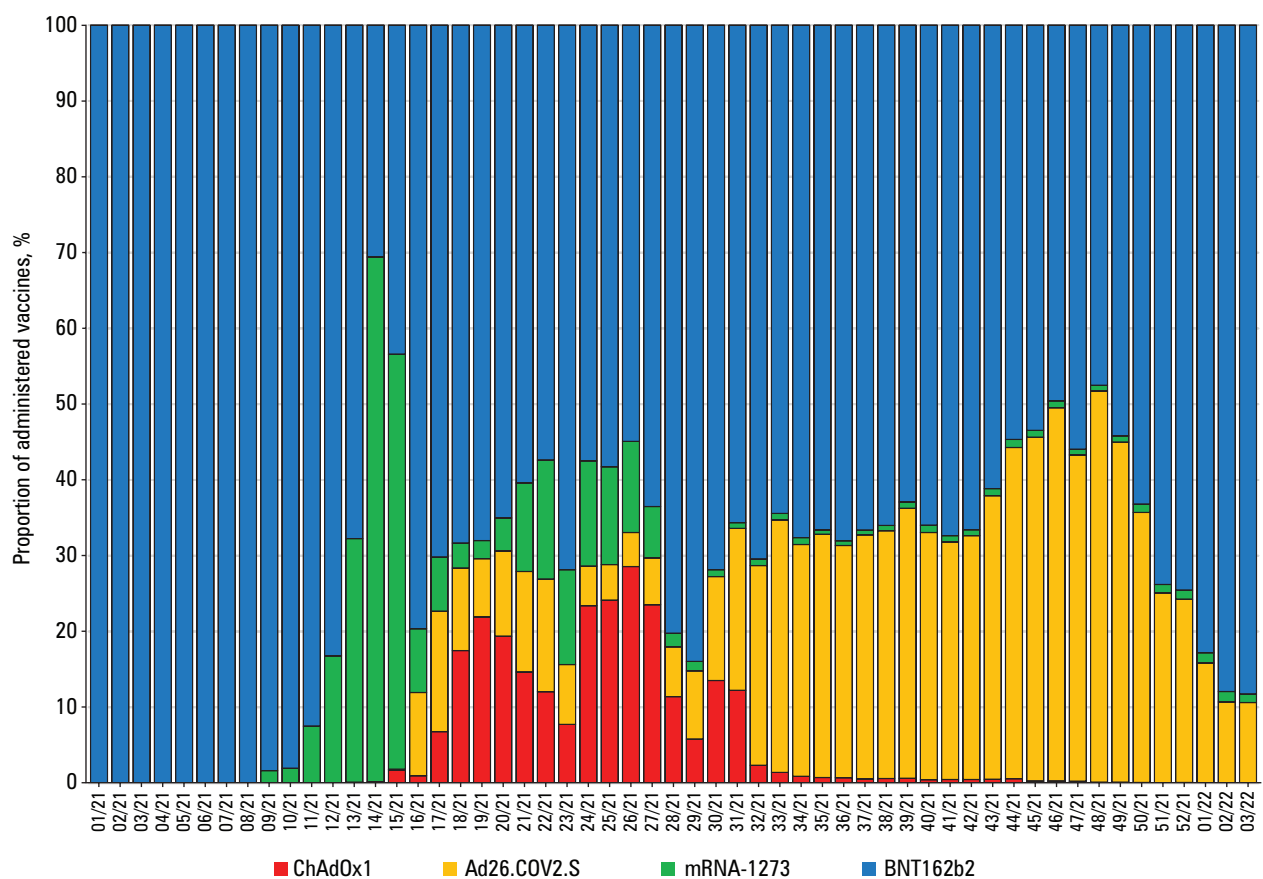
**FIGURE 5** presents a temporal increase in the number of deaths in the vaccinated group over the weeks following achievement of full vaccination status. It shows a gradual loss of protection following vaccination.



**FIGURE 2** Vaccination status with all vaccines (**A**) and the BNT162b2 vaccine (**B**) across the study period

**DISCUSSION** The aim of this retrospective, registry-based study was to evaluate the vaccination rate and the effectiveness of the BNT162b2 vaccine between 2021 and 2022 in Poland. During

the study period, the vaccination rate was almost 60%, with the majority of the citizens being vaccinated with the BNT162b2 vaccine. We showed that the weekly average effectiveness of the BNT162b2



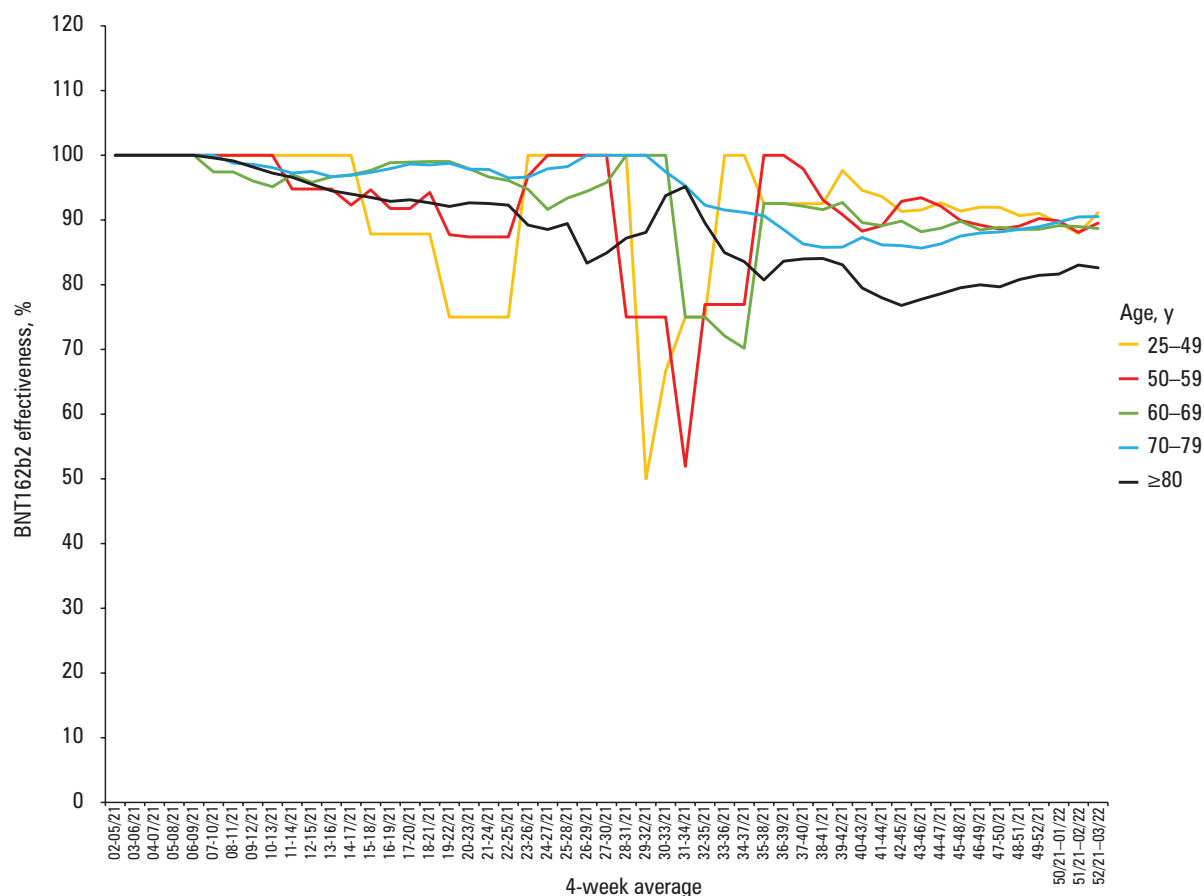
**FIGURE 3** Proportion of vaccines administered across the study period

**TABLE 1** Summary of the vaccination status and vaccine effectiveness stratified by age category

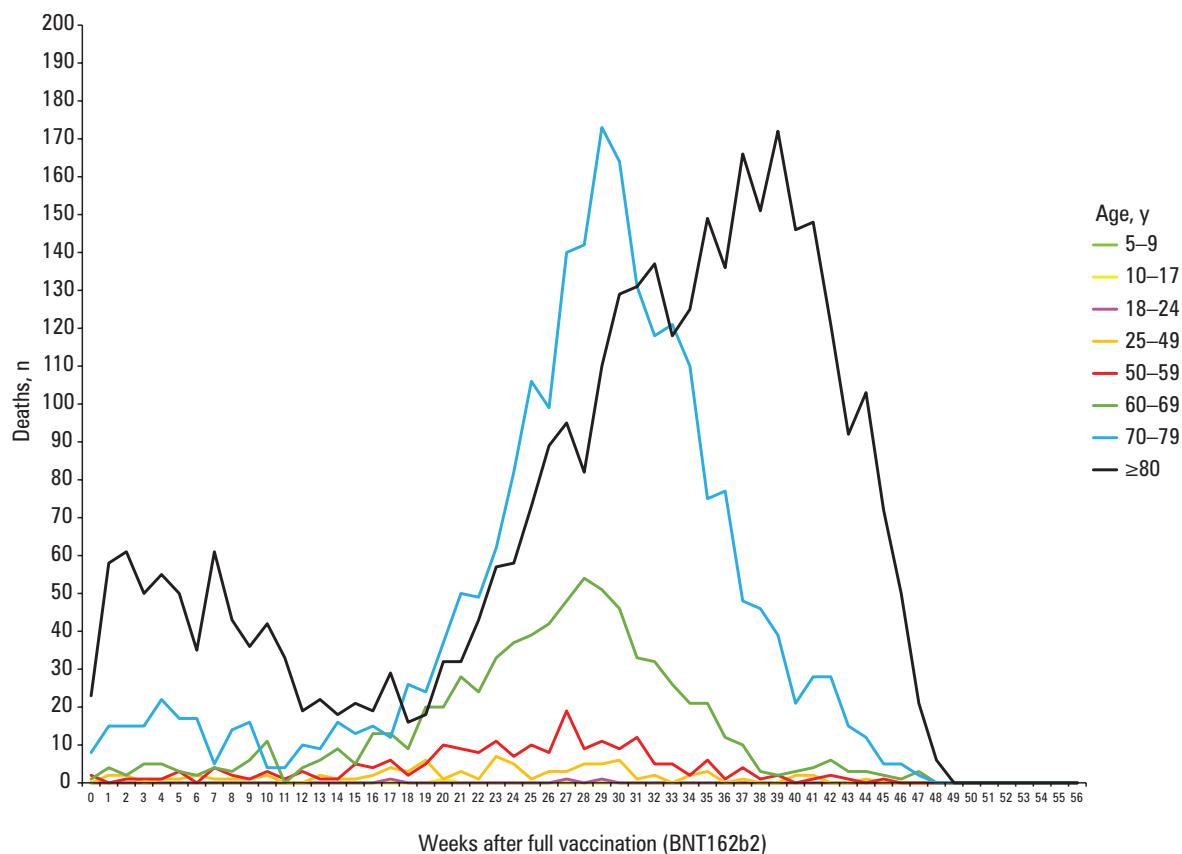
Age category, y	Population, n	Nonvaccinated, n	Fully vaccinated, n (%)	Fully vaccinated with BNT162b2, n (%)	Mortality among nonvaccinated, n (rate per 100000)	Mortality among fully vaccinated with BNT162b2, n (rate per 100000)	P value	Overall effectiveness of full vaccination, %	Deaths that could have been prevented by vaccination, n
5–9	1910470	1632724	28400 (1.49)	28394 (1.49)	16 (0.98)	0	–	100	16
10–17	3140933	1847205	1017539 (32.4)	1014494 (32.3)	9 (0.49)	0	–	100	9
18–24	2688690	1143376	1475454 (54.88)	924805 (34.4)	42 (3.67)	3 (0.32)	<0.001	91.17	38
25–49	14216985	5724338	8227364 (57.87)	5042304 (35.47)	2482 (43.36)	82 (1.63)	<0.001	96.25	2389
50–59	4605466	1457323	3086998 (67.03)	2061854 (44.77)	3850 (264.18)	189 (9.16)	<0.001	96.53	3716
60–69	5185843	1302817	3833968 (73.93)	2234215 (43.08)	13530 (1038.52)	680 (30.43)	<0.001	97.07	13133
70–79	2930420	541237	2383313 (81.33)	2113597 (72.13)	18869 (3486.27)	2122 (100.4)	<0.001	97.12	18326
≥80	1683970	571528	1098696 (65.24)	1021843 (60.68)	26014 (4551.66)	3243 (317.37)	<0.001	93.03	24200
Total	36362777	14220548	21151732 (58.17)	14441506 (39.71)	64812 (455.76)	6319 (43.76)	<0.001	90.4	61803

vaccine in preventing COVID-19-associated death was very high, and amounted to 92.6%. It varied significantly depending on the age group, and ranged from 89.08% in individuals aged 80 years

and older up to 100% in the patients aged 5 to 17 years. We estimated that the 100% vaccination rate could have saved approximately 60 000 additional lives. Our results suggest that vaccination



**FIGURE 4** Effectiveness of the BNT162b2 vaccine in the study groups aged from 25 to over 80 years from week 2 of 2021 to week 3 of 2022



**FIGURE 5** Number of COVID-19-associated deaths in the patients vaccinated with the BNT162b2 vaccine aged from 5 to over 80 years from week 53 of 2020 to week 3 of 2022, including the number of weeks after full vaccination



is an effective way of preventing death, even in the populations with moderate vaccination rate.

One of the most important determinants of the vaccination program effectiveness is the vaccination rate. In the European Union countries it varies significantly from 30% in Bulgaria to 86.6% in Portugal. The reasons for such vast differences in the national compliance are variable and include capacity of the health care system, quality of the national campaign promoting the vaccine, the government attitude toward vaccines, and the level of national health awareness and education. The achievement of high vaccine coverage during the COVID-19 pandemic was additionally hindered by numerous organizations and public figures raising doubts and fear about the safety of COVID-19 vaccines among the public. Unfortunately, Poland remains one of the countries with the lowest vaccination rates in the European Union, despite wide availability of the vaccines. Our analysis shows that the vaccination rate was the highest in the individuals aged 60–79 years, and decreased gradually in younger subgroups. Highly similar trends were observed in the other countries. This is most likely related to a higher risk of severe COVID-19 among elderly patients, and their stronger motivation to protect themselves.

Our observations concerning the VE in preventing COVID-19–associated deaths cover the data from other countries with a similar or higher vaccination rate. A study carried out in Scotland, including 114 706 cases of SARS-CoV-2 infection between April and September 2021, indicated that the effectiveness of the BNT162b2 vaccine in preventing death in people who received 2 doses was 90%.<sup>7</sup> In the United States, during the Delta wave in October and November 2021, unvaccinated persons had 12.7 times higher risk of death than those fully vaccinated.<sup>8</sup> Also a Qatar study<sup>9</sup> confirmed high level of protection (93.4%) against COVID-19–associated death in 2021 in people vaccinated with 2 doses of the BNT162b2 vaccine.

In the analyzed period, all available vaccines were based on the original coronavirus strain from Wuhan, China, which raised doubts about their effectiveness against various variants of SARS-CoV-2, in particular the Alpha and Delta variants, as they differ significantly from the original strain. Both Alpha and Delta variants were designated as Variants of Concern (VOCs) by the WHO. In comparison with the original Wuhan strain, the Alpha variant (B.1.1.7) has 23 mutations, with 8 mutations in the virus spike protein. Three of them are thought to have the largest potential biologic effect, such as increased expression of the coronavirus S protein binding to angiotensin-converting enzyme 2 (ACE2) cell receptor and immune response evasion.<sup>10</sup> The Delta variant (B.1.617.2), which first appeared in India, has 23 mutations as compared with the Alpha strain. Two of them allow the variant to attach more firmly to ACE2 receptors, while the other

may allow the Delta variant to evade the host immunity. In summary, these mutations make the Delta variant up to 60% more transmissible than the Alpha variant, exceptionally infectious, and capable of evading neutralizing antibodies in previously infected or vaccinated people.<sup>11–13</sup>

Due to such differences, especially concerning the Delta variant, one may expect that the VE against the nonoriginal variants would also be lower. In fact, both the BNT162b2 and ChAdOx1 vaccines have been reported to have reduced effectiveness in the individuals infected with the Delta variant, as compared with the other VOCs. The effectiveness of 2 doses of the BNT162b2 vaccine was 93.7% in the people infected with the Alpha variant, and 88% in those infected with the Delta variant.<sup>14</sup> Although 2 doses of the mRNA vaccines prevented COVID-19–associated hospital admissions with the same effectiveness (85%) in the case of both Alpha and Delta variants, the mRNA vaccines differed in their ability to protect people against COVID-19–associated deaths related to these 2 variants. For example, among the patients hospitalized for COVID-19, the effectiveness of the mRNA vaccine (2 doses) in preventing progression to invasive mechanical ventilation or death was 76% for the Alpha variant, and only 44% for the Delta variant.<sup>15,16</sup> However, other papers presented different results. For example, according to Nasreen et al,<sup>17</sup> VE against severe outcomes after 2 doses of BNT162b2 was estimated at above 90% against both Alpha and Delta variants. In general, in people who received 2 doses of the BNT162b2 vaccine, a 5-fold increase in death cases was noticed in those infected with the Delta variant, as compared with those infected with the Alpha variant.<sup>17</sup> In comparison with the Alpha wave in Poland, we have noted a 3- to 5-fold increase in death cases in the fully vaccinated people during the Delta wave, depending on age, which is in line with the above statement.

The effectiveness of vaccines depends not only on the coronavirus variant, but also on the age of the vaccinated people. It is known that in older persons the response to immunization decreases with age,<sup>18–21</sup> and for this reason the effectiveness of COVID-19 vaccines against symptomatic infection is generally lower in older adults (≥60 years) than in younger citizens (<60 years) for most of the VOCs.<sup>17</sup> In our report, we also highlighted the decline in patient response to the BNT162b2 vaccine with age, with a gradual increase in the percentage of deaths especially in people aged 80 years and older. Similar results were reported by Sheikh et al,<sup>7</sup> who found that during the Delta wave the percentage of death cases at 14 or more days from the second dose of the BNT162b2 vaccine was 0% for the 18–39 years old age group, 0.06% for those aged 40–59 years, and 1.23% for the group of people older than 60 years. It needs to be pointed out that, despite gradual decrease of the VE with age, it remains very high and amounts to 93% in the oldest age group.

This is the first report on the course of the COVID-19 vaccination program in Poland. It comprehensively describes the vaccination rate and efficiency of the BNT162b2 vaccine in preventing COVID-19-associated deaths. Its main strength is the inclusion of all Polish citizens and the use of publicly available information from governmental databases. Such an approach ensures the validity of our analyses and allows for drawing valuable conclusions for further research and management of the ongoing vaccination program.

We are aware of several limitations of this study. First, the databases did not include data on booster doses, which could potentially lead to overestimation of the VE in our study. Second, the data on side effects of the vaccination were not available, and we were unable to include this important aspect in our report. Third, due to limited testing for COVID-19, the number of infections and COVID-19-related deaths could have been underestimated. Fourth, we decided only to report the data on the BNT162b2 vaccine to avoid overcomplication of the manuscript. This decision was based on the fact that nearly 70% of the fully vaccinated individuals in Poland received this vaccine. Finally, due to registry-based design of the study, we were unable to include some potentially important variables, such as comorbidities and genetic variant of the virus, in our analysis.

In this retrospective report based on the registry data of all Polish citizens, we confirmed that despite only moderate vaccination rate, the BNT162b2 vaccine provided excellent protection against COVID-19-associated deaths. This observation was consistent in all age groups, however, there was an evident decline in the VE in older individuals. Considering the large estimated number of lives already saved by COVID-19 vaccines in Poland, we strongly believe that efforts should be made to further promote the vaccination program in our country to prepare the health care system for upcoming waves of the pandemic.

## ARTICLE INFORMATION

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**CONTRIBUTION STATEMENT** ŁP, KP, RH, ACS, and WS conceived the concept of the study. ŁP, KP, RH, ACS, and WS contributed to the design of the research. ŁP was responsible for data collection. ŁP and KP analyzed the data. All authors participated in preparation of the manuscript draft. All authors edited and approved the final version of the manuscript.

**CONFLICT OF INTEREST** None declared.

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