

The effectiveness of Vaxzevria and CoronaVac vaccines: A nationwide longitudinal retrospective study of 61 million Brazilians (VigiVac-COVID19).

Short Title: **Effectiveness of Vaxzevria and CoronaVac vaccines in Brazil**

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Abstract

Background

High rates of virus transmission and the presence of variants of concern can affect vaccine effectiveness (VE). Both conditions occur in low-income countries, which primarily use viral vector or inactivated virus vaccine technologies. However, few VE analyses have been conducted in such countries, and most lack the power to evaluate effectiveness in subgroups, such as the elderly.

Methods

The present retrospective cohort study evaluated the effectiveness of Vaxzevria and CoronaVac vaccines for COVID-19-related infection in 60,577,870 Brazilian vaccinees from January 18 to June 30, 2021.

Study outcomes included documented infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), Covid-19–related hospitalization, ICU admission and death. We estimated VE for each outcome as one minus the hazard ratio using Cox regression adjusted for age, sex, Brazilian deprivation index, and month/region of dose administration.

Results

Vaccination with Vaxzevria or CoronaVac was found to be effective against SARS-CoV-2 infection and highly effective against hospitalization, ICU admission and death in individuals up to 79 years. From 80-89 years of age, 91.2 (95CI: 89.1-92.9) VE against death was seen in Vaxzevria-vaccinated individuals versus 67.3 (95CI: 63.6-70.6) for Coronvac. Above 90 years, 70.5 (95CI: 51.4-82.1) protection was conferred to Vaxzevria-vaccinated individuals versus 35.4 (95CI: 23.8-45.1) in Coronavac-vaccinated individuals

Conclusions

Both vaccines demonstrated overall effectiveness against severe COVID-19 up to 80 years of age. Our results suggest that individuals aged 90 years or older may benefit from an expedited third booster dose. Ongoing evaluations, including any additional vaccines authorized, are crucial to monitoring long-term vaccine effectiveness.

Background

Several COVID-19 vaccines have proved efficacious, and many of them are being extensively used around the world.¹⁻⁴ While high-income countries preferentially administer mRNA-based vaccines, lower- and middle-income countries have employed vaccines based on viral vectors or inactivated virus technologies. A timely evaluation of the effectiveness of the currently available vaccines across different regions is essential for a comprehensive understanding of vaccine impact, considering significant variations in vaccination schedules, virus transmission and the emergence of viral variants, in addition to social and cultural standards and local health system conditions.

Brazil is one of the countries most affected by the pandemic, with high rates of transmission. The Brazilian COVID-19 vaccination program initially relied on the vaccines Vaxzevria/Fiocruz (previously Oxford-AstraZeneca or ChAdOx-1), approved in 181 countries, and Sinovac's CoronaVac/Butantan, approved in 39 countries.⁵ The recommended interdose interval in Brazil for Vaxzevria is 12 weeks versus 2-4 weeks for CoronaVac. The period between doses of Vaxzevria has varied in several countries.⁷ However, CoronaVac has been applied at distinct intervals,^{1,8} making direct comparisons difficult. Additionally, several early publications on vaccine effectiveness (VE) evaluated only the initial dose or were limited to analyzing effectiveness against symptomatic infection^{9,10} and hospitalization^{10,11}, i.e., ICU admission and death were not addressed.

Nationwide evaluations of the effectiveness of COVID-19 vaccines in Brazil offers advantages, as this country's large population is distributed throughout several regions with considerable differences in socio-economic aspects and access to medical facilities. Nonetheless, data collection systems are identical throughout the entire country, offering a comprehensive source of data to perform a countrywide VE evaluations. The COVID-19 vaccination campaign was initiated nationwide on January 18, 2021. By June, a large number

of vaccinees had received either Vaxzevria/Fiocruz or CoronaVac/Butantan vaccines, allowing for a detailed evaluation of the effectiveness of both vaccines while considering several outcomes and stratified age ranges, making it possible to examine in detail specific age effects previously not investigated.

A significant issue regarding the VE of vaccines against COVID-19 is the degree of circulation of distinct SARS-CoV-2 variants of concern (VOC) in different regions. During the course of the present study, the Gamma variant was the most frequent in all regions of Brazil.¹² Importantly, the literature contains few reports on the VE of Vaxzevria and Coronavac against the Gamma variant.^{1,10,13}

The present study aimed to evaluate the effectiveness of Vaxzevria and Coronavac vaccines in 60,577,870 Brazilian vaccinee with respect to several different outcomes: COVID-19 related infection, hospitalization, ICU admission and death, between January 18 and June 30, 2021.

Methods

Study design and datasets

We conducted a retrospective cohort using individual-level information on demographic, clinical characteristics, and SARS-COV-2 laboratory tests from the Brazilian federal health registries. The Brazilian Ministry of Health Department of Informatics (DATASUS) provided unidentified datasets of the COVID-19 Vaccination Campaign dataset (SI-PNI), the Acute Respiratory Infection Suspected Cases dataset (e-SUS Notifica), and the National Epidemiological Surveillance System registry for Severe Acute Respiratory Infection/Illness (SIVEP-Gripe). A key-coded individual identification number present in the three datasets was used for a deterministic linkage and then removed from the resulting linked dataset used

in our analyses. No personally identifiable data was accessed at any stage. Codebooks, scripts and public dataset version will be available at <https://vigivac.fiocruz.br>

SI-PNI is a data warehouse run by DATASUS with all the vaccine doses administered by health services in Brazil. From SI-PNI, we extracted information on the COVID-19 vaccine received either Sinovac CoronaVac or Vaxzevria (under the names AstraZeneca/Fiocruz or Covishield/ChAdOx1-S), and the dates of the first and second doses. Overall and age-specific Brazilian population estimates for 2021 corrected the all-cause deaths reported in 2020 overall and age were retrieved from the Brazilian Institute of Geography and Statistics.¹⁴

Open version of the SI-PNI dataset is available at [opendatasus-SI PNI](#).

The e-SUS Notifica is a national online health surveillance information system where acute respiratory infections cases and COVID-19 suspected or confirmed cases are registered, and has been used as a data source for epidemiological research.¹⁵ Open version of e-SUS Notifica is available at [opendatasus-eSUS Notifica](#).

SIVEP-Gripe is the national system used to register SARI-related hospitalizations and deaths caused by influenza or other respiratory viruses. The system is a registry for new respiratory infections since the H1N1 pandemic in 2009 and widely used as a source for epidemiological studies.¹⁶⁻¹⁸ All COVID-19 related SARI hospitalizations and deaths (independent of hospitalization) are registered in the system. Open version of the 2021 SIVEP-Gripe dataset is available at [opendatasus-SIVEP](#)

From both SIVEP-Gripe and eSUS-Notifica, we extracted information on the date of symptom onset, RT-PCR, and antigen test results for SARS-CoV-2, and from SIVEP-Gripe, we got data of hospitalization, admission to ICU, and hospitalization outcome (discharge or death).

Study population

We included all individuals who received the COVID-19 vaccine first dose between January 18th, 2021, and June 30th, 2021. The study individuals were followed retrospectively to assess infection, hospitalization, admission to ICU, and death with a laboratory-confirmed diagnosis of SARS-CoV-2 up to June 30th, 2021.

We excluded individuals (i) vaccinated with vaccines besides Vaxzevria or CoronaVac, (ii) with inconsistent vaccine records (i.e., individuals who received the second dose without the first dose, received doses from different vaccines or interval between doses less than 14 days), (iii) with confirmed COVID-19 before the date of vaccine administration, and (iv) with missing data for essential covariates (i.e., sex or age).

Exposure and outcomes

We defined vaccination status for each vaccine based on the time elapsed since the administration of a vaccine dose:

1. ≤ 13 days after the first dose (the reference period)
2. ≥ 14 days after the first dose and without the second dose (partially vaccinated)
3. ≥ 14 days after the second dose (fully vaccinated)

We defined the period up to 13 days after the first dose as the reference period for VE estimation based on results of a Phase III randomized controlled trial⁸ and three test-negative studies.^{11,19,20} The time-lapsed between the date of the first dose and the development of an effective immune response is used to detect bias in test-negative case-control studies to estimate vaccine effectiveness, the theoretical frame for such use has been discussed by Hitchings et al.²¹ We also analyzed vaccine effectiveness for 1 to 13 days after the second dose, with the results presented in supplementary table S1).

Laboratory confirmation of COVID-19 with a positive RT-PCR or antigen test result) was required for inclusion in the analyses. The outcomes analyzed were infection, hospitalization, admission to an intensive care unit (ICU), and death by COVID-19. We considered the time

between day one of the first or second vaccination up to the symptom's onset for each outcome. Individuals whose symptoms started on the same day of the first vaccination dose were assigned one day of follow-up time. Death was considered at any time regardless of prior hospitalization. ICU admission was considered at any time point between the admission and the discharge or death dates.

Statistical analyses

In the primary analysis, we used a Cox regression model to estimate the hazard ratio (HR) of COVID-19 infection, hospitalization, ICU admission, and death for partially and fully vaccinated individuals. The model was adjusted for age, sex, region of residence, socioeconomic status, and month of the 1st dose. We used the Brazilian Deprivation Index (*Índice Brasileiro de Privação-IBP*), a municipality-level measure of material deprivation, as an indicator of socioeconomic status.²¹ We estimated vaccine effectiveness (VE) as $1 - \text{HR}$, obtained from a model including all covariates, and reported as a percentage. We also reported the crude VE for each outcome. In addition, we performed a stratified analysis by age groups (<60, 60–69, 70–79, 80–89, ≥ 90 years) to investigate whether VE was modified by age.

To assess the robustness of our findings, we repeated the principal analysis defining as the reference period the time elapsed up to 10 days after the date of the first dose, as it is expected that the vaccines' protection increases with time. Additionally, we examined the VE for hospitalization, ICU admission and death using clinical suspected cases besides laboratory confirmed ones.

Analyses were performed using the R statistical software (R Core Team) and its H2O package.^{23,24} Descriptive statistics were presented as frequencies and percentages. We used

the 95% confidence intervals (CI) of the estimated measures of association for interpreting the findings.

RESULTS

From January 18 to June 30, 2021, 61,783,842 individuals received at least one dose of one of the two COVID-19 vaccines analyzed in this study, and 60,577,870 (98.1%) met the eligibility criteria and were included in the analysis (Figure 1). The majority (63.8%, n=38,664,633 individuals) received at least one dose of Vaxzevria and the remaining (36.2%, n=21,933,237 individuals) received at least one dose of CoronaVac. The majority of our cohort comprised women (56.1%) and individuals aged 60 years or older (44.4%). Compared to individuals that received CoronaVac, individuals that received Vaxzevria were younger (29.3% vs. 70.9% of individuals aged 60 years or older), and a lower proportion had completed the full vaccine schedule (10.6% vs. 82.7%). Vaccination with CoronaVac occurred mainly from January to April 2021, while Vaxzevria was administered predominantly after March 2021 (Figure 2). Among those who received the second dose, the median time between the first and second doses was 85 days (IQR 83–90) for Vaxzevria and 27 days (IQR 21–28) for CoronaVac. Individuals who received at least one dose of Vaxzevria or CoronaVac were mostly women (54.6% vs. 58.7% respectively) and from the southeast region of the country (44.1% vs. 46.3%, respectively) (Table 1).

Table 2 shows the COVID-19 VE analysis results, including number of events and incidence rate per 1000 person-days and supplementary table S1 shows the crude and adjusted VE analysis. We observed that individuals with full vaccination schedule (i.e., ≥ 14 days after the second dose) with Vaxzevria had a 70.0% (95% CI 68.6 to 71.3) lower risk of infection, 86.8% (95% CI 85.2 to 88.2) lower risk of hospitalization, 88.1% (95% CI 85.4 to 90.3) lower risk of ICU admission, and 90.2% (95% CI 88.3 to 91.8) lower risk of death. Partial vaccination (i.e., ≥ 14 days after the first dose up to the second dose) with Vaxzevria was

associated with a 32.7% lower risk of infection (95% CI 31.9 to 33.5) and at least 50% lower risk of hospitalization (51.7%; 95% CI 50.4 to 52.9), ICU admission (53.6%; 95% CI 51.4 to 55.6), and death (49.3%; 95% CI 47.0 to 51.5). Complete vaccination with CoronaVac was associated with a 54.2 (95% CI 53.4-55.0) lower risk of infection, 72.6% (95% CI 71.6 to 73.6) lower risk of hospitalization, 74.2% (95% CI 72.6 to 75.7) lower risk of ICU admission, and 74.0% (95% CI 72.6 to 75.3) lower risk of death. Partial vaccination with CoronaVac was associated with less than 50% of reduction in the risk of infection (16.2%; 95% CI 15.1 to 17.4), hospitalization (26.5%; 95% CI 24.6 to 28.4), ICU admission (28.1%; 95% CI 24.9 to 31.1), and death (29.4%; 95% CI 26.7 to 32.0).

When stratifying the analysis by age, complete vaccination with Vaxzevria or CoronaVac presented a similar VE within all age groups, with the exception among individuals aged 90 years or older (Table S2, Figure 3).

In the analysis using the reference period of up to 10 days after the first dose, we found VE point and interval estimates similar to those found in the primary analysis for both Vaxzevria and Coronavac vaccines (Table S3). The results using all clinical suspected and laboratory confirmed cases for the outcomes of hospitalization, ICU admission and death were qualitatively equal to those found in primary analysis (Table S4).

DISCUSSION

Here we present nationwide results on the effectiveness of vaccination with CoronaVac/Butantan and Vaxzevria/Fiocruz after the first six months of the vaccination campaign in Brazil. Analyzing data from almost 61 million individuals vaccinated with at least one dose, our results demonstrate strong evidence of 70.0% and 54.2% protection against infection after full vaccination with Vaxzevria and CoronaVac, respectively. Vaxzevria offered approximately 90% effectiveness against hospitalization, ICU admission

and death, while CoronaVac provided approximately 75% protection following full vaccination.

Our findings regarding the Coronovac/Butantan vaccine are compatible with a previous Brazilian efficacy study²⁴, but lower than the 83.5% protection reported by a Turkish efficacy trial.⁸ The effectiveness determined by a cohort study in Chile was also higher than our findings for infection (66.5% vs. 54.2%) as well as hospitalization (87.5% vs. 72.6%).

Differences between the study in Chile and the present analyses of Brazilian vaccinees may be partially explained by the higher frequency of younger individuals in the Chile study (51.2% vs. 29.1% of individuals younger than 60 years old). During the vaccination campaign, Brazil experienced health system collapse in several states, which may have influenced death rates, especially between February and May, likely affecting CoronaVac estimates more markedly due to its greater availability of this vaccine in the early stages of the vaccination program. Another reason for these differences could be the increased circulation of the Gamma lineage detected in these countries, which has been estimated at 28.6% in Chile and 69.6% in Brazil during both study periods.^{1,12} In plasma samples obtained from individuals fully vaccinated with CoronaVac, a reduced capacity to neutralize the Gamma variant was observed.¹ Furthermore, 9.9% of the Brazilian population was fully vaccinated from January to May 2021, compared to almost 35.4% of Chile's population. This may have contributed to lower viral transmission in Chile compared to Brazil.¹

For Vaxzevria, our findings of 70.0% effectiveness against infection exceeded the levels of 66.7% effectiveness reported in a combined analysis of four clinical trials conducted in the UK, South Africa, and Brazil.⁷ Effectiveness against hospitalization was consistent with the 80% and 89% protection observed in studies in Scotland³ and England,¹¹ respectively.

Additionally, our findings support the high level of protection offered by Vaxzevria despite the abundant circulation of the Gamma variant in Brazil during the period studied. Few

studies have reported on the VE of Vaxzevria in populations infected by VOCs.^{1,9,10,13,20}

Studies analyzing effectiveness against VOCs have mainly focused on protection against symptomatic infection or hospitalization.^{9,10,13} Taken together, the findings reported herein combined with data in the literature confirm a consistently high rate of protection against moderate to severe COVID-19 in real-world studies, despite abundant circulation of VOCs.

Protection was shown to vary according to age group. The VE of CoronaVac/Butantan was close to 80% against death in individuals aged up to 79 years of age. However, a reduction in effectiveness was observed after 80 years of age, with only 35.4% protection against death seen in individuals over 90. In contrast, the Vaxzevria/Fiocruz vaccine achieved close to 90% protection against death in individuals aged less than 90 years, while a VE of 70.5% was found in those older than 90 years of age. It is reasonable to attribute the observed reduction in effectiveness to immunosenescence, which is commonly associated with a higher frequency of comorbidities, and may imply higher death rates. In the context of limited vaccine availability, the precise identification of age limits at which point immune protection becomes impaired can provide valuable evidence to inform public health measures.

Considering the current scenario in Brazil, our findings demonstrate the eventual need for a vaccine booster dose in individuals aged 80 years or older who received CoronaVac, as well as for individuals over 90 years immunized with Vaxzevria.

The differences evidenced in effectiveness between Vaxzevria and CoronaVac may be related to the distinct technologies used by each of these two products, as well as how they influence immunogenicity. Both vaccines analyzed herein activate immunological mechanisms and trigger a neutralizing antibody response against viral particles. However, CoronaVac, a whole-cell inactivated vaccine, elicits a less potent cellular response than Vaxzevria, an adenoviral-vectored vaccine.²⁵ Additionally, Vaxzevria was shown to induce a higher peak neutralizing antibody response than CoronaVac.²⁷ Thus, the intrinsic

characteristics of each formulation may serve to explain differences observed in both clinical trials and vaccine effectiveness studies.^{1,26,28}

A relevant strength of our study is its large sample size, due to the use of the complete dataset covering the Brazilian COVID-19 vaccination campaign from January to June 2021. This large sample allowed us to identify the age limits in which immune protection becomes impaired, especially with regard to CoronaVac. Sensitivity analyses further confirmed the robustness of our findings. However, our study is also subject to some limitations. First, as VE was estimated using observational data, our analysis is subject to data availability and, therefore, to potential confounders. Although our analyses were not controlled for comorbidities, crude and adjusted VE estimates were similar. In addition, comorbidities have been identified as the causal pathway between age and COVID-19 severity. Therefore, by controlling for age, we are also indirectly controlling for comorbidities.²⁹ Second, in contrast to many VE studies, the reference period used herein for comparison purposes was 1-13 days after vaccination. Although using early post-vaccination as a reference may underestimate VE, previous studies have used a similar approach and obtained VE results similar to those found in clinical trials.^{30,31} The early post-vaccination period can also be used as a bias indicator related to differences in SARS-CoV-2 infection risk. Additionally, the effectiveness results of the present report are similar, in the pertinent age ranges, to reports on both vaccines using distinct approaches.^{1,19,20} Finally, we also performed sensitivity analysis, which demonstrated similar results when a 0-10 day reference period was applied.

Using the data available in Brazil, we estimated overall VE for each vaccine evaluated as well as by age group. Vaxzevria/Fiocruz and CoronaVac/Butantan were both shown to be highly protective against severe COVID-19 in the population aged up to 80 years, yet due to decreased VE an early booster dose may be considered for those over 80 years of age who received CoronaVac, and especially for individuals aged over 90 years regardless of which of

these two vaccines were administered. Despite high population adherence, the vaccination campaign is evolving unevenly throughout Brazil, and continuous monitoring of VE in the current context may provide sound evidence to inform public health measures.

ETHICAL CONSIDERATIONS

The Brazilian National Commission in Research Ethics approved the research protocol (CONEP approval number 4.921.308). The study was considered exempt from informed consent; no human health risks were identified. All work presented here used unidentified secondary data in accordance with the Brazilian Personal Data Protection General Law (LGPD). Data was manipulated in a secure computing environment, ensuring protection against data leakage and records reidentification.

DECLARATION OF INTERESTS

VO, VB, MB, and MB-N are employees from Fiocruz, a federal public institution, which manufactures Vaxzevria in Brazil, through a full technology transfer agreement with AstraZeneca. Fiocruz allocates all its manufactured products to the Ministry of Health for the public health service (SUS) use. All other authors report no potential competing interest.

FUNDING

This study was partially supported by a donation from the "[Fazer o bem faz bem](#)" program.

DATA SHARING

We used third-party data, provided by the Brazilian Ministry of Health. Any request for access to the data shall be directed to DATASUS - Ministry of Health Brazil:

<https://datasus.saude.gov.br/>

ACKNOWLEDGMENTS

The authors thank DATASUS for its excellent work in providing unidentified databases.

GW, MB, and MB-N are research fellows from CNPq, the Brazilian National Research Council. The authors would also like to thank Andris K. Walter for English language revision and manuscript copyediting assistance.

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TABLES AND FIGURES

Table 1. Demographic characteristics of individuals that received at the first dose of Vaxzevria and CoronaVac in Brazil between 18th January and 30th June 2021.

	Vaxzevria/Fiocruz			CoronaVac/Butantan		
	Persons with only one dose N=34,556,983 n (%)	Persons with two doses N=4,107,650 n (%)	Total N=38,664,633 n (%)	Persons with only one dose N=3,794,753 n (%)	Persons with two doses N=18,138,484 n (%)	Total N=21,933,237 n (%)
Sex (Female)	18,603,771 (53.8)	2,509,503 (61.1)	21,113,274 (54.6)	2,136,515 (56.3)	10,739,832 (59.2)	12,876,347(58.7)
Age group						
<20	279,896 (0.8)	18,880 (0.5)	298,776 (0.8)	36,246 (1.0)	57,185 (0.3)	93,431 (0.4)
20-29	2,369,858 (6.9)	284,973 (6.9)	2,654,831 (6.9)	294,281 (7.8)	832,301 (4.6)	1,126,582 (5.1)

30-39	3,935,033 (11.4)	427,267 (10.4)	4,362,300 (11.3)	351,089 (9.3)	1,204,701 (6.6)	1,555,790 (7.1)
40-49	7,143,476 (20.7)	386,696 (9.4)	7,530,172 (19.5)	988,384 (26.0)	1,091,683 (6.0)	2,080,067 (9.5)
50-59	12,198,475 (35.3)	280,890 (6.8)	12,479,365 (32.3)	671,336 (17.7)	863,722 (4.8)	1,535,058 (7.0)
60-69	7,899,957 (22.9)	751,488 (18.3)	8,651,445 (22.4)	631,203 (16.6)	5,211,550 (28.7)	5,842,753 (26.6)
70-79	401,161 (1.2)	591,043 (14.4)	992,204 (2.6)	611,335 (16.1)	6,701,411 (36.9)	7,312,746 (33.3)
80-89	284,210 (0.8)	1,234,312 (30.0)	1,518,522 (3.9)	163,675 (4.3)	1,712,040 (9.4)	1,875,715 (8.6)
≥90	44,917 (0.1)	132,101 (3.2)	177,018 (0.5)	47,204 (1.2)	463,891 (2.6)	511,095 (2.3)
Region of residence						
<i>Central West</i>	2,568,166 (7.4)	342,173 (8.3)	2,910,339 (7.5)	246,240 (6.5)	1,359,139 (7.5)	1,605,379 (7.3)

<i>Northeast</i>	825,655 (2.4)	1,074,931 (26.2)	1,900,586 (4.9)	769,299 (20.3)	4,412,161 (24.3)	5,181,460 (23.6)
<i>North</i>	2,453,059 (7.1)	507,337 (12.4)	2,960,396 (7.7)	242,527 (6.4)	1,165,657 (6.4)	1,408,184 (6.4)
<i>Southeast</i>	15,479,240 (44.8)	1,582,019 (38.5)	17,061,259 (44.1)	2,083,624 (54.9)	8,077,669 (44.5)	10,161,293 (46.3)
<i>South</i>	5,621,171 (16.3)	575,822 (14.0)	6,196,993 (16.0)	427,859 (11.3)	3,021,915 (16.7)	3,449,774 (15.7)
<i>Missing</i>	178,789 (0.5)	25,368 (0.6)	204,157 (0.5)	25,204 (0.7)	101,943 (0.6)	127,147 (0.6)
Brazilian						
Municipal						
Deprivation Index						
<i>I</i>	7,140,436 (20.7)	776,055 (18.9)	7,916,491 (20.5)	788,353 (20.8)	3,973,481 (21.9)	4,761,834 (21.7)

2	6,616,814 (19.1)	712,784 (17.4)	7,329,598 (19.0)	994,456 (26.2)	3,456,814 (19.1)	4,451,270 (20.3)
3	7,071,108 (20.5)	833,540 (20.3)	7,904,648 (20.4)	729,322 (19.2)	3,751,664 (20.7)	4,480,986 (20.4)
4	6,925,602 (20.0)	853,682 (20.8)	7,779,284 (20.1)	595,008 (15.7)	3,580,458 (19.7)	4,175,466 (19.0)
5	6,624,234 (19.2)	906,221 (22.1)	7,530,455 (19.5)	662,410 (17.5)	3,274,124 (18.1)	3,936,534 (17.9)
<i>Missing</i>	178,789 (0.5)	25,368 (0.6)	204,157 (0.5)	25,204 (0.7)	101,943 (0.6)	127,147 (0.6)

The study participants were included if they received first dose of CoronaVac or Vaxzevria between January 18 and June 30, 2021. The Brazilian Municipal Deprivation Index works as proxy for socioeconomic status.

Table 2. Vaccine effectiveness of Vaxzevria and CoronaVac in Brazil for COVID-19 infection, hospitalization, ICU admission, and death.

	Vaxzevria/Fiocruz				CoronaVac/Butantan			
	Person-days	Events	Incidence per 1000 person- days	VE % (95% CI)*	Person-days	Events	Incidence per 1000 person- days	VE % (95% CI)*
Infection								
<i>Reference period</i>	474,317,595	76,780	0,1619	Ref	272,340,929	47,523	0,1745	Ref
<i>Partially vaccinated</i>	1,183,986,976	119,195	0.1007	32.7 (31.9-33.5)	431,038,009	55,495	0.1287	16.2 (15.1-17.4)
<i>Fully</i>	98,266,804	6,271	0.0638	70.0 (68.6-	1,184,435,889	108,998	0.0920	54.2 (53.4-55.0)

<i>vaccinated</i>				71.3)					
Hospitalization									
<i>Reference</i>									
<i>period</i>	474,679,253	18,420	0.0389	Ref	272,540,206	15,080	0.0553	Ref	
<i>Partially</i>									
<i>vaccinated</i>	1,189,453,888	20,998	0.0177	51.7 (50.4-52.9)	434047110	14,484	0.0334	26.5 (24.6-28.4)	
<i>Fully</i>									
<i>vaccinated</i>	99,464,137	574	0.0058	86.8 (85.2-88.2)	1192845239	20,299	0.0170	72.6 (71.6-73.6)	
ICU admission									
<i>Reference</i>									
<i>period</i>	474,760,394	6,272	0.0132	Ref	272,599,778	5,643	0.0207	Ref	
<i>Partially</i>									
	1,190,575,743	7,129	0.0060	53.6 (51.4-	435,127,028	5,291	0.0122	28.1 (24.9-31.1)	

<i>vaccinated</i>				55.6)				
<i>Fully vaccinated</i>	99,558,609	184	0.0018	88.1 (85.4-90.3)	1,194,037,275	6,971	0.0058	74.2 (72.6-75.7)
Death								
<i>Reference period</i>	474,761,099	6,255	0.0131	Ref	272,587,083	7,529	0.0276	Ref
<i>Partially vaccinated</i>	1,190,384,840	8,518	0.0072	49.3 (47.0-51.5)	434,742,763	6,988	0.0161	29.4 (26.7-32.0)
<i>Fully vaccinated</i>	99,567,659	249	0.0025	90.2 (88.3-91.8)	1,193,883,495	9,600	0.0080	74.0 (72.6-75.3)

Reference period: ≤ 13 days after the first dose; Partially vaccinated: ≥ 14 days after the first dose and without the second dose; Fully vaccinated: ≥ 14 days after the second dose. ICU denotes intensive care unit.

* Cox regression model adjusted for age, sex, region of residence, month of administration of first dose and municipal deprivation level.

Table S1. Crude and adjusted Vaccine effectiveness of Vaxzevria and CoronaVac in Brazil for COVID-19 infection, hospitalization, ICU admission and death.

	Vaxzevria/Fiocruz		CoronaVac/Butantan	
	CRUDE VE % (95% CI)	ADJUSTED VE % (95% CI)*	CRUDE VE % (95% CI)	ADJUSTED VE % (95% CI)*
Infection				
<i>Reference period</i>	—	—	—	—
<i>Partially vaccinated</i>	27.4 (26.5-28.2)	34.0 (33.2-34.7)	14.1 (12.9-15.3)	16.4 (15.2-17.5)
<i>Fully vaccinated until 13 days</i>	49.0 (47.3-50.6)	56.9 (55.3-58.5)	38.2 (37.2-39.1)	40.3 (39.4-41.2)
<i>Fully vaccinated</i>	63.2 (61.7-64.7)	70.0 (68.6-71.3)	52.5 (51.7-53.3)	54.2 (53.4-55.0)
Hospitalization				
<i>Reference period</i>	—	—	—	—
<i>Partially vaccinated</i>	45.3 (43.8-46.7)	52.2 (50.9-53.4)	24.1 (22.1-26.0)	26.6 (24.6-28.4)
<i>Fully vaccinated until 13 days</i>	53.8 (50.5-56.9)	69.6 (67.2-71.8)	55.0 (53.6-56.4)	57.3 (56.0-58.6)
<i>Fully vaccinated</i>	79.0 (76.5-81.2)	86.8 (85.2-88.2)	71.0 (70.0-72.0)	72.6 (71.6-73.6)
ICU admission				
<i>Reference period</i>	—	—	—	—
<i>Partially vaccinated</i>	46.5 (44.0-48.9)	54.0 (51.8-56.0)	25.3 (22.1-28.4)	28.1 (24.9-31.1)

<i>Fully vaccinated until 13 days</i>	51.5 (45.6-56.8)	69.2 (65.0-72.8)	55.8 (53.5-57.9)	58.1 (55.9-60.1)
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<i>Fully vaccinated</i>	80.2 (76.0-83.7)	88.1 (85.4-90.3)	72.6 (70.9-74.2)	74.2 (72.6-75.7)
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Death

<i>Reference period</i>	—	—	—	—
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<i>Partially vaccinated</i>	39.7 (37.0-42.3)	49.3 (47.0-51.5)	26.9 (24.2-29.6)	29.4 (26.7-32.0)
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<i>Fully vaccinated until 13 days</i>	31.9 (24.9-38.3)	72.1 (69.1-74.9)	56.2 (54.3-58.1)	58.7 (56.9-60.4)
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<i>Fully vaccinated</i>	74.8 (70.0-78.8)	90.2 (88.3-91.8)	72.1 (70.7-73.5)	74.0 (72.6-75.3)
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* Cox regression model adjusted for age, sex, region of residence, month of administration of first dose and municipal deprivation level.

Table S2. Vaccine effectiveness of Vaxzevria and CoronaVac in Brazil by age groups for COVID-19 infection, hospitalization, ICU admission and death.

	Vaxzevria/Fiocruz					CoronaVac/Butantan				
	<60	60-69	70-79	80-89	≥90	<60	60-69	70-79	80-89	≥90
Infection										
<i>Partially vaccinated</i>	38.8 (37.9-39.7)	23.1 (21.3-24.9)	25.9 (20.3-31.1)	28.2 (24.5-31.7)	-43.0 (-71.2 to -19.5)	13.8 (11.6-16.0)	15.4 (13.0-17.8)	25.0 (23.1-26.9)	1.5 (-3.0 to 5.9)	-19.3 (-30.5 to -9.2)
<i>Fully vaccinated until 13 days</i>	54.4 (51.9-56.8)	72.2 (68.2-75.8)	60.9 (56.4-65.0)	57.9 (55.1-60.5)	21.5 (1.4-37.6)	31.1 (29.2-32.9)	38.1 (36.1-40.0)	52.5 (51.2-53.8)	37.1 (33.9-40.1)	9.1 (0.3-17.2)
<i>Fully vaccinated</i>	62.5 (60.2-64.7)	78.5 (73.3-82.6)	79.2 (75.7-82.2)	78.3 (76.4-80.1)	46.9 (30.9-59.3)	44.6 (43.0-46.2)	55.9 (54.3-57.4)	61.9 (60.7-63.1)	57.1 (54.7-59.5)	31.7 (24.4-38.2)
Hospitalization										
<i>Partially vaccinated</i>	64.1 (62.6-65.5)	44.9 (42.4-47.4)	32.9 (25.2-39.8)	32.9 (28.0-37.4)	-31.1 (-66.1 to -3.4)	33.7 (27.1-39.7)	29.5 (25.8-33.0)	32.5 (29.9-35.1)	8.2 (2.1-13.8)	-16.2 (-31.2 to -2.9)

<i>Fully vaccinated until 13 days</i>	83.8 (77.7-88.2)	83.3 (77.3-87.8)	71.9 (66.4-76.5)	66.6 (63.3-69.7)	34.9 (11.1-52.4)	67.1 (62.8-70.8)	60.2 (57.6-62.6)	62.2 (60.4-63.9)	42.7 (38.6-46.6)	12.4 (0.6-22.8)
<i>Fully vaccinated</i>	94.2 (89.8-96.6)	91.7 (84.3-95.6)	88.4 (84.6-91.2)	86.9 (84.9-88.7)	54.9 (35.4-68.5)	84.2 (81.3-86.7)	78.2 (76.3-79.8)	74.0 (72.6-75.4)	63.0 (59.9-66.0)	32.7 (22.8-41.3)
ICU admission										
<i>Partially vaccinated</i>	65.1 (62.5-67.6)	48.9 (44.8-52.7)	37.4 (25.1-47.7)	33.9 (25.6-41.3)	-35.4 (-110.9 to 13.1)	32.1 (19.4-42.8)	29.0 (23.1-34.5)	33.1 (28.8-37.1)	18.1 (8.6-26.6)	-27.8 (-59.6 to -2.3)
<i>Fully vaccinated until 13 days</i>	83.2 (70.2-90.6)	82.4 (71.2-89.3)	69.3 (59.5-76.7)	68.0 (62.3-72.8)	5.8 (-60.4 to 44.7)	69.1 (61.1 - 75.4)	61.7 (57.7-65.4)	60.9 (57.9-63.6)	46.4 (39.5-52.5)	11.3 (-12.3 to 29.9)
<i>Fully vaccinated</i>	95.5 (85.8-98.6)	93.2 (78.7-97.9)	87.4 (80.5-91.9)	89.3 (86.0-91.8)	39.7 (-11.7-67.5)	80.8 (74.5-85.6)	78.7 (75.8-81.3)	75.7 (73.5-77.8)	65.1 (59.9-69.7)	37.2 (18.4-51.6)
Death										
<i>Partially vaccinated</i>	64.8 (61.8-67.6)	45.4 (41.0-49.4)	37.1 (26.9-45.8)	38.1 (32.2-43.4)	-40.6 (-84.5 to -7.1)	41.7 (26.4-53.9)	35.7 (30.3-40.7)	38.2 (34.7-41.5)	10.1 (2.7-1.07)	-22.1 (-40.7 to -5.9)

<i>Fully vaccinated until 13 days</i>	80.7 (57.6-91.2)	88.5 (78.9-93.7)	77.2 (70.5-82.4)	71.3 (67.4-74.7)	45.2 (19.4-62.8)	66.1 (54.9-74.5)	64.1 (60.3-67.4)	65.5 (63.2-67.6)	46.9 (41.9-51.5)	10 (-4.4 to 22.4)
<i>Fully vaccinated</i>	93.3 (72.1-98.4)	89.6 (71.8-96.2)	92.5 (88.1-95.3)	91.2 (89.1-92.9)	70.5 (51.4-82.1)	76.5 (66.9-83.3)	78.7 (76.6-80.0)	78.3 (76.6-80.0)	67.3 (63.6-70.6)	35.4 (23.8-45.1)

*Obtained through Cox regression model adjusted for age, sex, region of residence, month of administration of first dose and municipal deprivation level

Table S3. Robustness analysis with different time windows as reference period

	Vaxzevria/Fiocruz VE % (95% CI)	CoronaVac/Butantan VE % (95% CI)
Reference Period:	0-10 days	0-10 days
<i>Infection</i>		
<i>Partially vaccinated</i>	33.2 (32.3-34.0)	16.5 (15.2-17.8)
<i>Fully vaccinated until 13 days</i>	55.5 (53.7-57.3)	38.0 (36.9-39.0)
<i>Fully vaccinated</i>	69.8 (68.2-71.3)	54.6 (53.7-55.5)
<i>Hospitalization</i>		
<i>Partially vaccinated</i>	51.3 (49.9-52.7)	25.5 (23.4-27.6)
<i>Fully vaccinated until 13 days</i>	67.6 (64.8-70.1)	55.4 (53.8-56.8)
<i>Fully vaccinated</i>	86.0 (84.1-87.6)	72.5 (71.4-73.6)
<i>ICU admission</i>		
<i>Partially vaccinated</i>	53.7 (51.3-56.0)	27.8 (24.3-31.1)
<i>Fully vaccinated until 13 days</i>	67.2 (62.4-71.3)	56.7 (54.2-59.0)
<i>Fully vaccinated</i>	87.4 (84.3-89.9)	74.1 (72.3-75.8)
<i>Death</i>		
<i>Partially vaccinated</i>	48.2 (45.6-50.6)	28.8 (25.8-31.6)
<i>Fully vaccinated until 13 days</i>	70.4 (66.8-73.7)	57.9 (55.8-59.9)
<i>Fully vaccinated</i>	89.2 (86.9-91.1)	73.7 (72.1-75.2)

Table S4: Percentage of events with laboratory confirmation and VE using all cases (laboratory and clinical suspected)

	Vaxzevria/Fiocruz				Coronavac/Butantan			
	Events- Laboratory Confirmed	Events-Confirmed or Clinical Suspected	% Confirmed	VE* (95% CI)	Events- Laboratory Confirmed	Events-Confirmed or Clinical Suspected	% Confirmed	VE* (95% CI)
Hospitalization								
<i>Reference period</i>	18,420	23,368	78.8	Ref	15,080	19,672	76.6	Ref
<i>Partially vaccinated</i>	20,998	27,946	75.1	50.7 (49.6-51.9)	14,484	19,182	75.5	25.5 (23.8-27.2)
<i>Fully vaccinated</i>	574	845	67.9	85.8 (84.3-87.1)	20,299	26,836	75.6	71.5 (70.6-72.4)
ICU admission								
<i>Reference period</i>	6,272	7,693	81.5	Ref	5,643	7,176	78.6	Ref
<i>Partially vaccinated</i>	7,129	9,164	77.8	52.4 (50.5-54.3)	5,291	6,875	77.0	26.9 (24.1-29.6)
<i>Fully vaccinated</i>	184	262	70.2	87.5 (85.1-89.5)	6,971	9,015	77.3%	73.2 (71.8-74.6)

Death

Reference period	6,255	7,749	80.7	Ref	7,529	9,608	78.4	Ref
Partially vaccinated	8,518	11,091	76.8	47.8 (45.7-49.8)	6,988	9,043	77.3	28.7 (26.3-31.0)
Fully vaccinated	249	359	69.4	89.5 (87.8-91.0)	9,600	12,262	78.2	73.4 (72.2-74.6)

*Obtained through Cox regression model adjusted for age, sex, region of residence, month of administration of first dose and municipal deprivation level

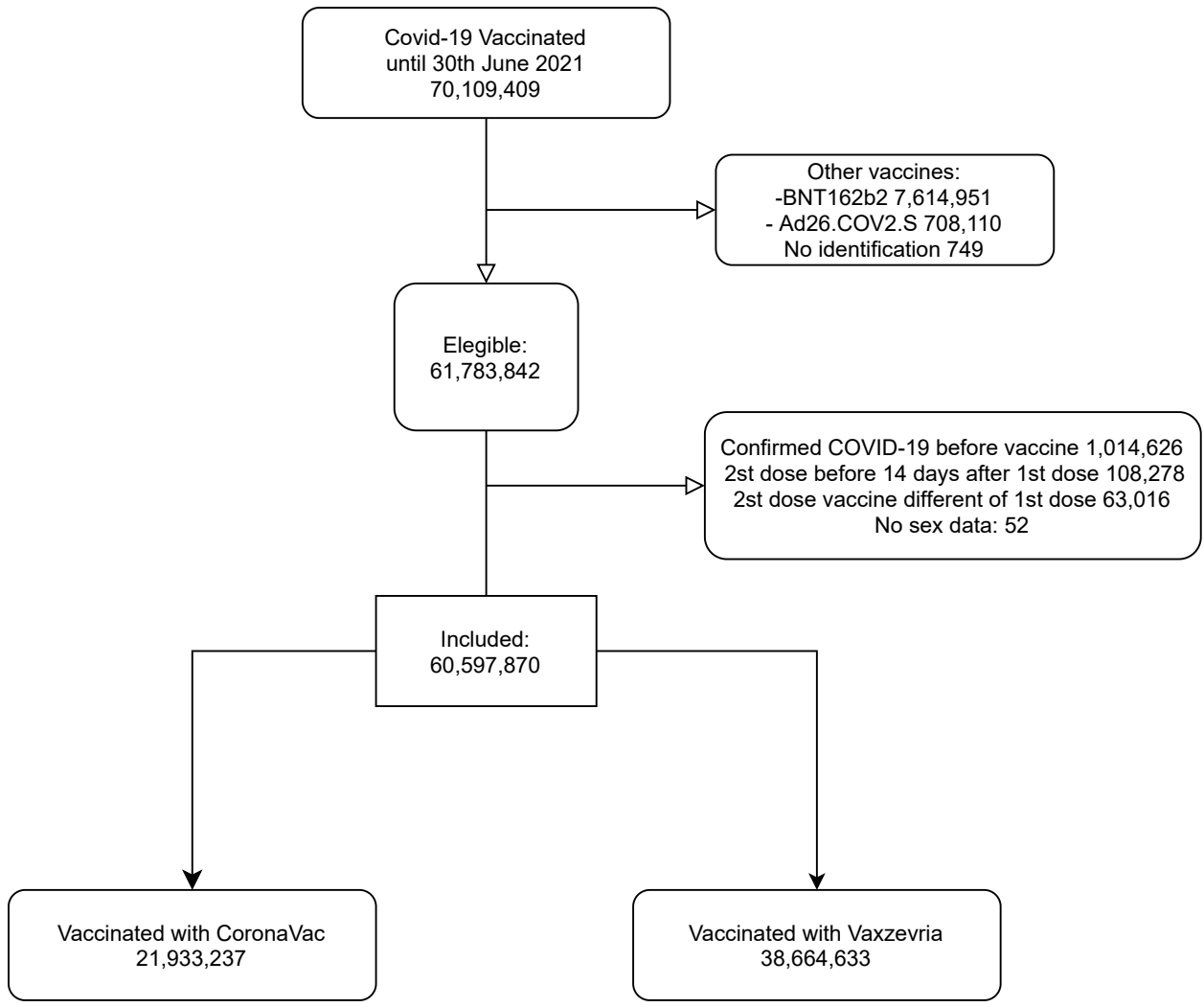
Figures legends

Figure 1. Flowchart of the selection of the study individuals vaccinated between 18th January and 30 June 2021. Eligible participants received at least one dose of CoronaVac or Vaxzevria vaccine between January 18 and June 30, 2021. We excluded persons with confirmed COVID-19 diagnosis in 2021 before the first dose and all persons with different vaccines from CoronaVac or Vaxzevria

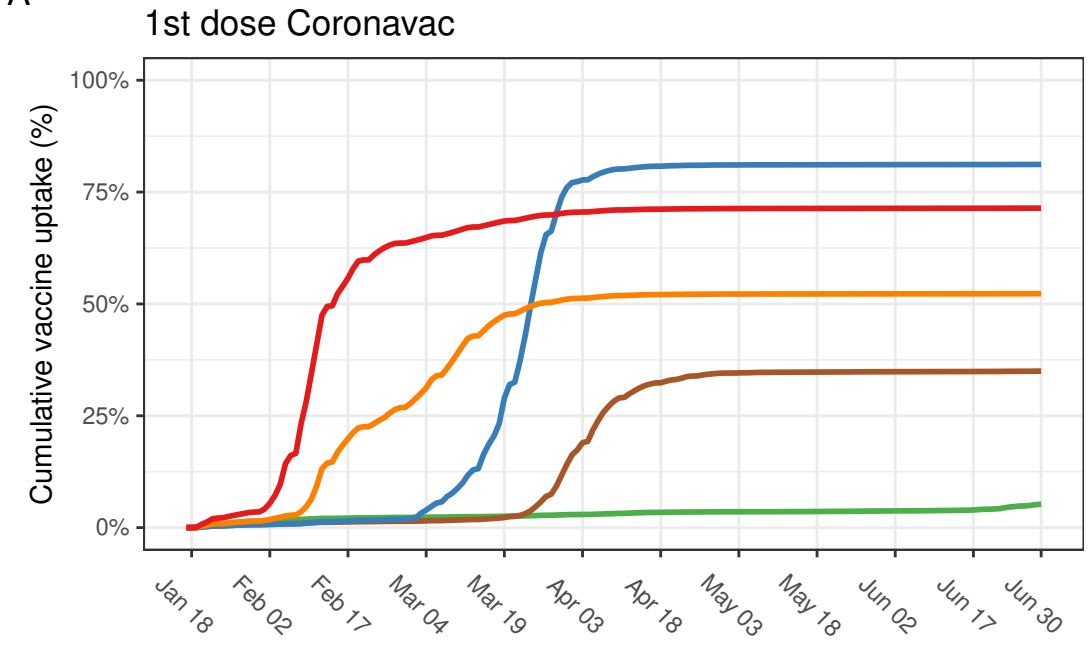
Figure 2. Coverage of first and second dose of CoronaVac and Vaxzevria in Brazil during the study period. The panels A, B, C and D shown the rate and coverage of the vaccination program regarding CoronaVac and Vaxzevria, A and C regarding first dose between January 18 and June 30 and panels B and D the second dose until 30 June 2021.

Figure 3. Vaccine effectiveness of Vaxzevria and CoronaVac in Brazil by age group. VE (1-Hazard Ratio) was obtained through Cox regression adjusted for age, sex, region of residence, the month of administration of first dose, and municipal deprivation level (IBP).

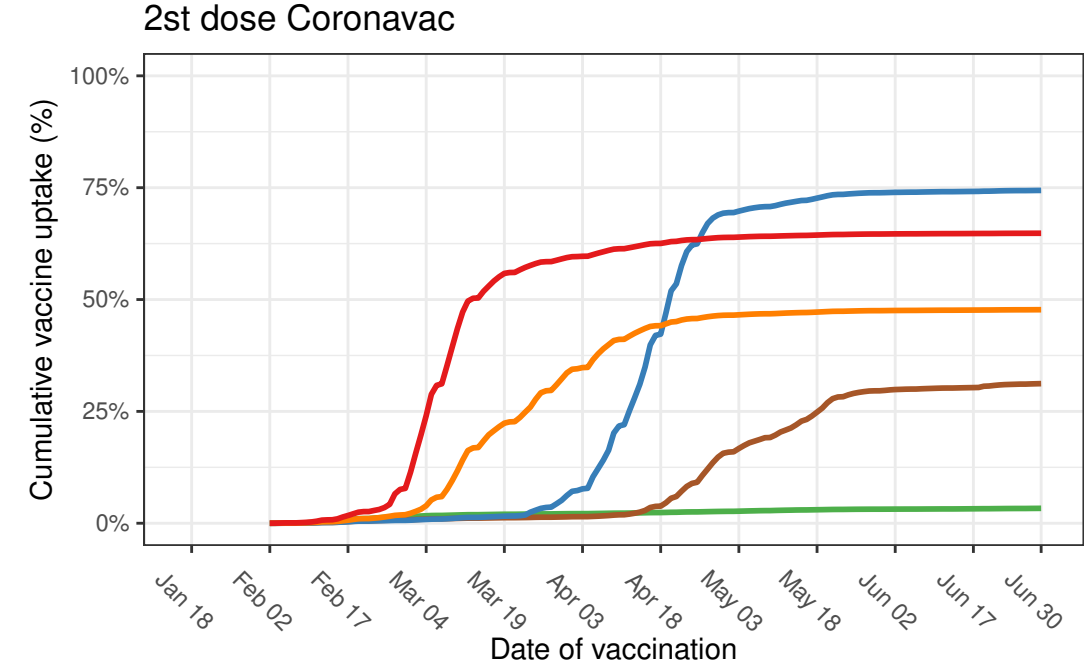
*The point estimate and confidence interval for ICU admission in ≥ 90 y.o. are 39.7 (95%CI - 11.7 to 67.5%), the large confidence interval is reflect of the small sample size and number of events in this group, 35 in the reference period and 33 in the fully vaccinated.



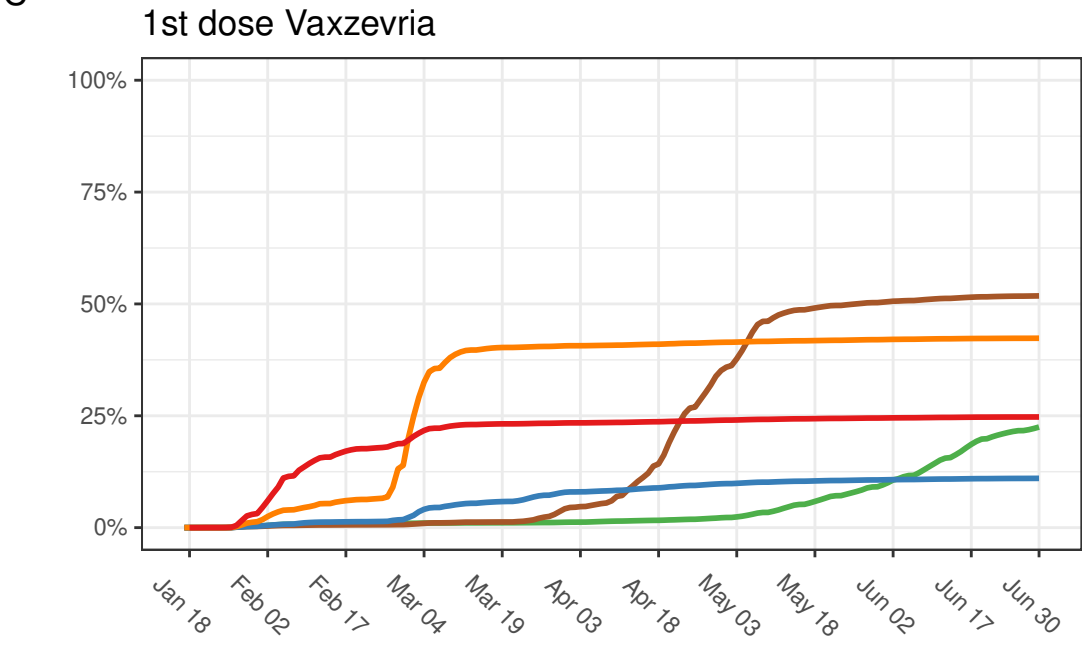
A



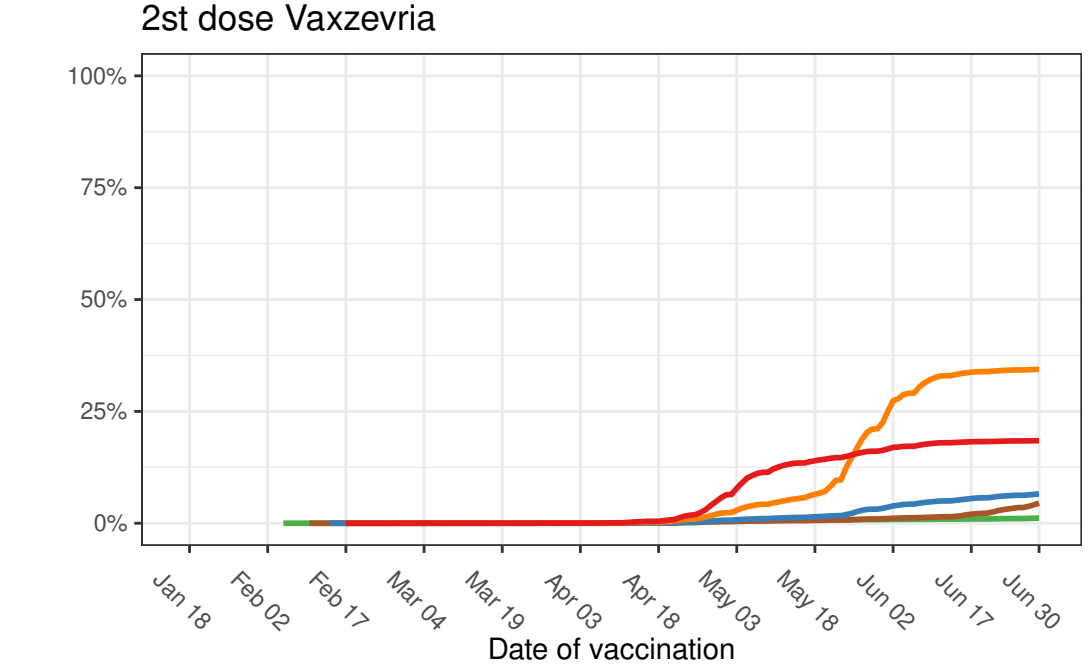
B



C



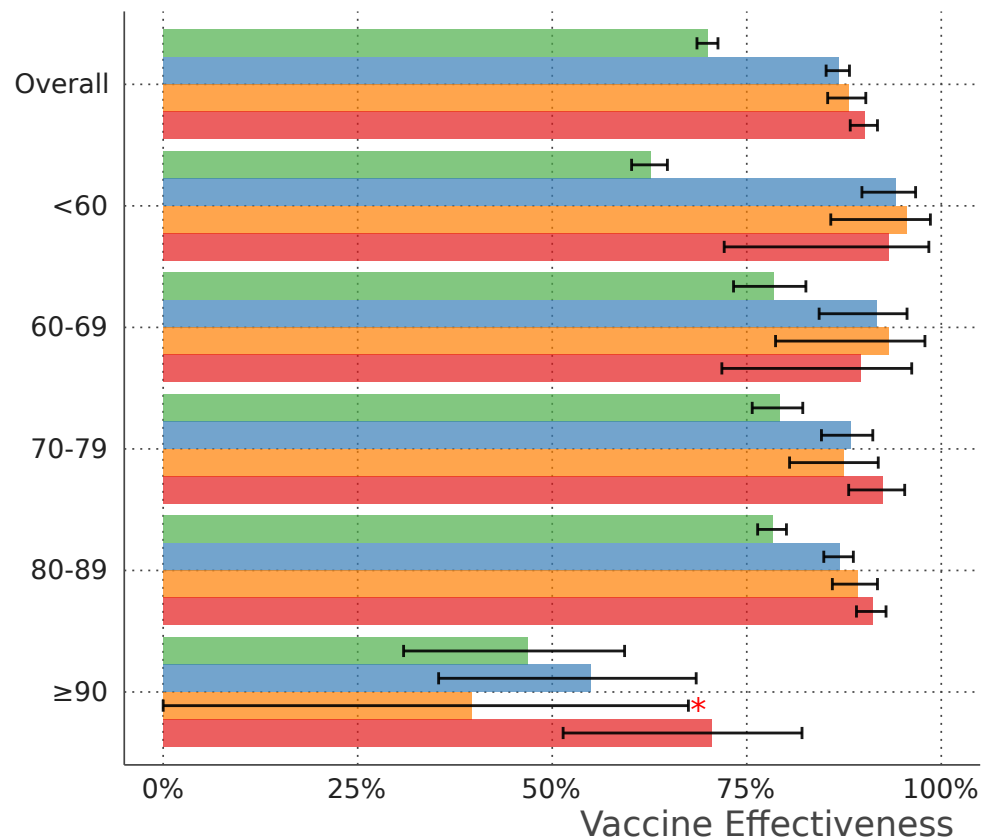
D



Age group — <60 — 60-69 — 70-79 — 80-89 — ≥90

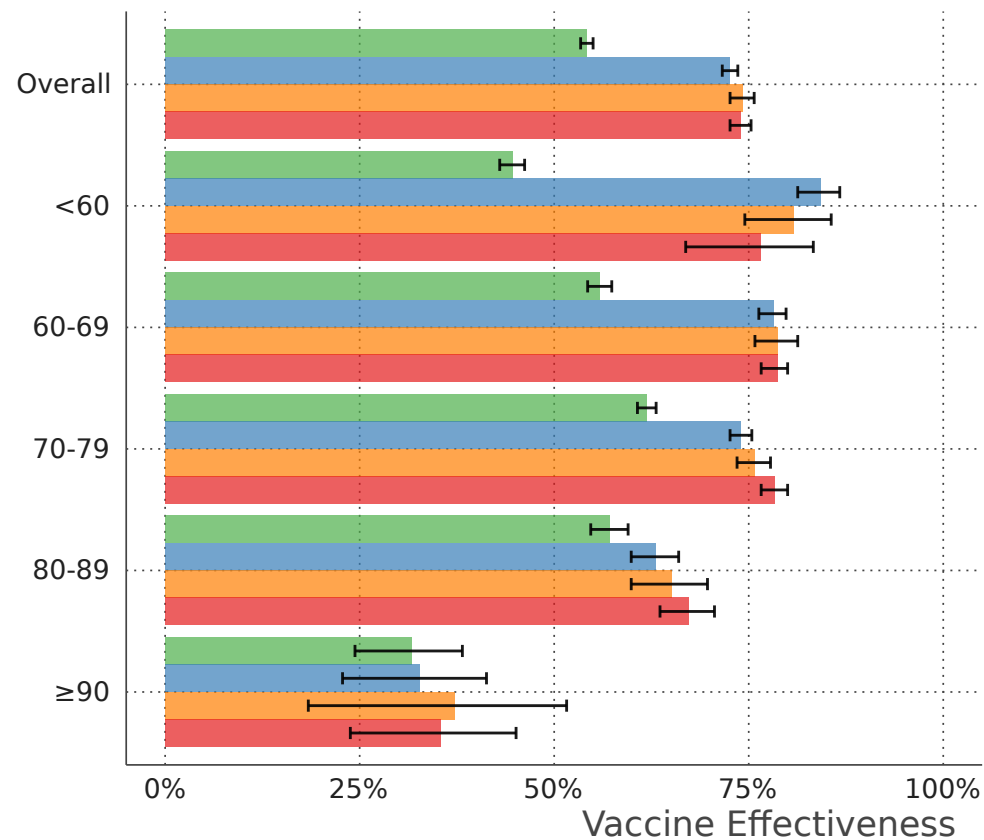
A

Vaxzevria



B

CoronaVac



Outcome Infection Hospitalization ICU admission Death