Effectiveness of the JN.1-adapted BNT162b2 COVID-19 Vaccine in High-Risk Groups against Hospitalization in Europe:

A Test-Negative Case-Control Study using the id.DRIVE Platform

Hannah R. Volkman PhD[1], Leonie de Munter PhD[2], Thao M.P. Tran PhD[3], Catia Marques MSc[4], Elisabeth J. Mesfun-Kap PhD[2], Laura Choi MPH[1], Hollie Dunford BSc[5], Srinivas Valluri PhD[1], Juan V. Hernandez-Villena MSc[3], Jingyan Yang DrPH[1], Sultan Abduljawad PhD[6], Irma Casas MD[7,10], Elisa Martró PhD[7,10], Beate Grüner MD[8], Ainara Mira-Iglesias PhD[9,10], Carlos Oñoro López MD[11], Oleguer Parés-Badell MD[12], Alejandro Orrico-Sánchez PhD[9,10,13], Susana Otero-Romero MD[12,14], Antoni Torres MD[15], Federico Martinón-Torres MD PhD[16], Jennifer L. Nguyen ScD[1]*, and Kaatje Bollaerts PhD[2]*

1 Pfizer Inc., New York, United States
2 P95 Clinical Epidemiology Services, Rotterdam, Netherlands
3 P95 Clinical Epidemiology Services, Leuven, Belgium
4 Pfizer Inc., Lisbon, Portugal
5 P95 Clinical Epidemiology Services, Durham, United States
6 BioNTech UK Ltd., London, United Kingdom
7 Hospital Universitari Germans Trias i Pujol, Badalona, Spain
8 University Hospital Ulm, Ulm, Germany
9 Fisabio, Valencia, Spain
10 CIBER-ESP, Instituto de Salud Carlos III, Madrid, Spain
11 Hospital Universitario La Paz, Madrid, Spain
12 Hospital Universitari Vall d'Hebron, Barcelona, Spain
13 Universidad Católica de Valencia San Vicente Mártir, Valencia, Spain
14 Universitat Autónoma de Barcelona, Barcelona, Spain
15 Hospital Clinic de Barcelona, Barcelona, Spain
16 Hospital Clínico Universitario de Santiago de Compostela, A Coruña, Spain
* These authors contributed equally

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Corresponding author: Hannah.Volkman@pfizer.com

Disclosure

This study was conducted as a collaboration between P95 and Pfizer. P95, co-coordinator of the id.DRIVE platform is the study sponsor. Pfizer is a partner in the id.DRIVE platform (https://iddrive.eu/) and funded this study. Dr. Volkman is an employee of Pfizer Inc. during the conduct of this study and holds stock and/or options in Pfizer Inc.

Background

2024–2025 vaccine effectiveness (VE) estimates published from Europe & United States[1–7]

- KP.2- and JN.1-adapted formulations were recommended for the 2024-2025 season

But there are limited data on VE in high-risk groups

- 1 study from the US (VISION)[3]
  - KP.2-adapted VE against COVID-19 hospitalization among adults ≥65 years with **immunocompromise: 40% (95% CI: 21 to 54)** at a range of 7 to 119 days since dose

No studies report VE among persons in other high-risk groups or with chronic conditions

1 Appaneal HJ, Lopes VV, Puzniak L et al. Early effectiveness of the BNT162b2 KP.2 vaccine against COVID-19 in the US Veterans Affairs Healthcare System. *Nature Comms*. 2025. DOI: https://doi.org/10.1038/s41467-025-59344-7
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3 Link-Gelles R, Chickery S, Webber A et al. Interim estimates of 2024–2025 COVID-19 Vaccine Effectiveness Among Adults Aged ≥18 years — VISION and IVY Networks, September 2024–January 2025. Morbidity and Mortality Weekly Report. 2025 DOI: http://dx.doi.org/10.15585/mmwr.mm7406a1
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Objective

Estimate the effectiveness of the JN.1-adapted BNT162b2 vaccine against COVID-19 hospitalization in high-risk groups in Europe using the id.DRIVE platform

The id.DRIVE platform

- Public-private partnership launched in 2024
  - Successor of COVIDRIVE, launched in 2021
- Large network of hospitals in Europe
- Comprehensive laboratory testing and genomic sequencing
- Data from medical records review, vaccine registries

id.DRIVE

id.DRIVE Methods[8]: a multi-site, test-negative case-control study

Study population

Adults ≥18 years of age & eligible for COVID-19 vaccination

Hospitalized with severe acute respiratory illness (SARI)
ECDC definition: Fever, cough, shortness of breath, anosmia, ageusia, or dysgeusia; symptom onset ≤14 days prior to admission

11 hospitals across Germany and Spain

Study period

Symptom onset 3 September 2024–31 May 2025

8 Methodology similar to previous season VE study: Nguyen JN, Mitratza M, Volkman HR et al. Effectiveness of the BNT162b2 XBB.1.5-adapted vaccine against COVID-19 hospitalization related to the JN.1 variant in Europe: a test-negative case-control study using the id.DRIVE platform. *eClinicalMedicine*. 2024. DOI: https://doi.org/10.1016/j.eclinm.2024.102995

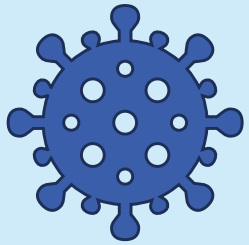
id.DRIVE Methods[8]: a multi-site, test-negative case-control study

Exposure status

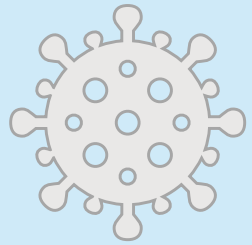
Exposed: Received ≥1 dose of BNT162b2 **JN.1-adapted** vaccine

Unexposed: Did not receive any COVID-19 vaccine in 2024–2025 season

Outcome status



Case: SARS-CoV-2 **positive** by PCR



Control: SARS-CoV-2 **negative** by PCR

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id.DRIVE Methods[8]: a multi-site, test-negative case-control study

Odds ratios (OR) and 95% Wald confidence intervals (95% CI) compare:

Odds of vaccination among test-positive cases **vs.** Odds of vaccination among test-negative controls

Estimated using multivariable penalised generalised estimating equation logistic regression adjusted for:

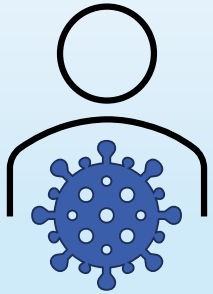
- Age
- Sex
- Symptom onset date
- Number of chronic conditions
- Influenza vaccination status

Adjusted vaccine effectiveness (VE) calculated as: $(1 - OR) \times 100\%$

8 Methodology similar to previous season VE study: Nguyen JN, Mitratza M, Volkman HR et al. Effectiveness of the BNT162b2 XBB.1.5-adapted vaccine against COVID-19 hospitalization related to the JN.1 variant in Europe: a test-negative case-control study using the id.DRIVE platform. *eClinicalMedicine*. 2024. DOI: https://doi.org/10.1016/j.eclinm.2024.102995

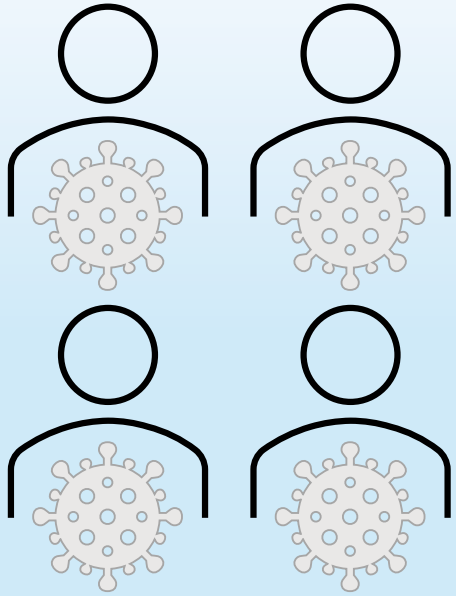
id.DRIVE Methods[8]: a multi-site, test-negative case-control study

Each case



Case

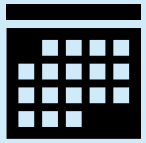
Matched with



Up to 4 Controls

Matched by

Study site



Symptom onset date

Two-week interval

8 Methodology similar to previous season VE study: Nguyen JN, Mitratza M, Volkman HR et al. Effectiveness of the BNT162b2 XBB.1.5-adapted vaccine against COVID-19 hospitalization related to the JN.1 variant in Europe: a test-negative case-control study using the id.DRIVE platform. *eClinicalMedicine*. 2024. DOI: https://doi.org/10.1016/j.eclinm.2024.102995

Results

3 September 2024–31 May 2025

764 hospitalized SARI patients included:

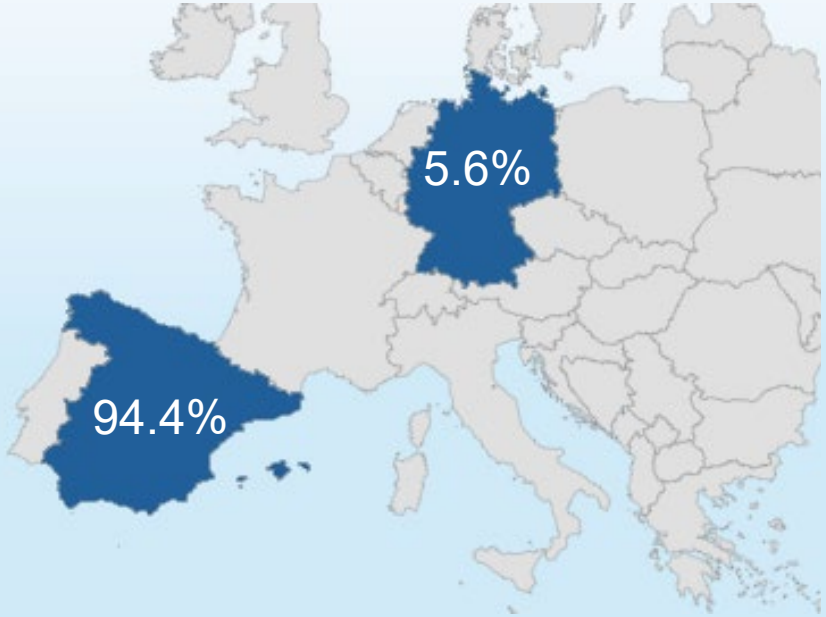
309 (40%) **vaccinated** patients received BNT162b2 JN.1-adapted COVID-19 vaccine

455 (60%) patients **did not receive any COVID-19 vaccine this season**

161 (21%) SARS-CoV-2 positive **cases**

603 (79%) SARS-CoV-2 negative **controls**

Country of hospitalization



SARI: severe acute respiratory infection

Figures 1 and 2. Epi curves of patients in id.DRIVE hospitalized with severe acute respiratory illnesses according to, Fig. 1) BNT162b2 JN.1-adapted vaccine receipt, and Fig. 2) Outcome status, Europe, 3 September 2024–31 May 2025

Figure 1: Vaccination status

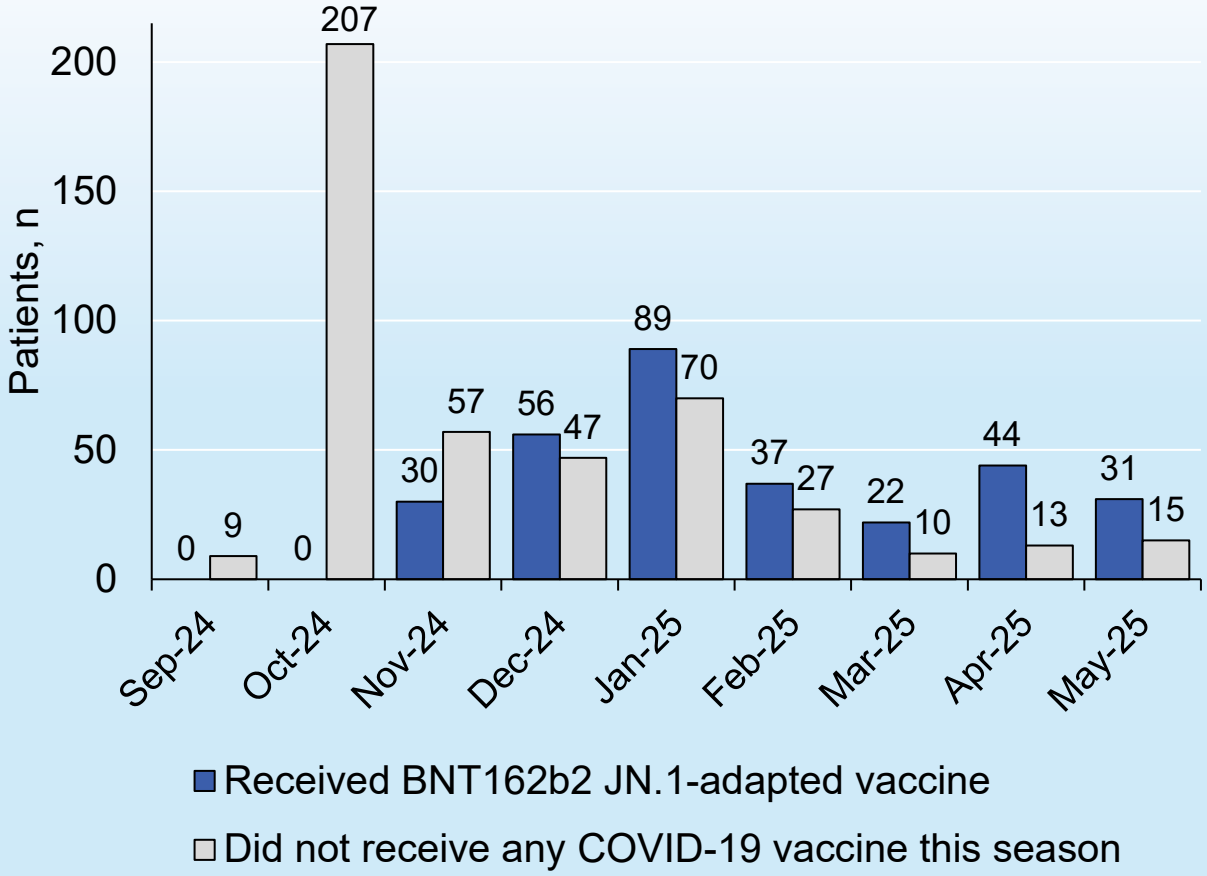


Figure 2: Outcome status

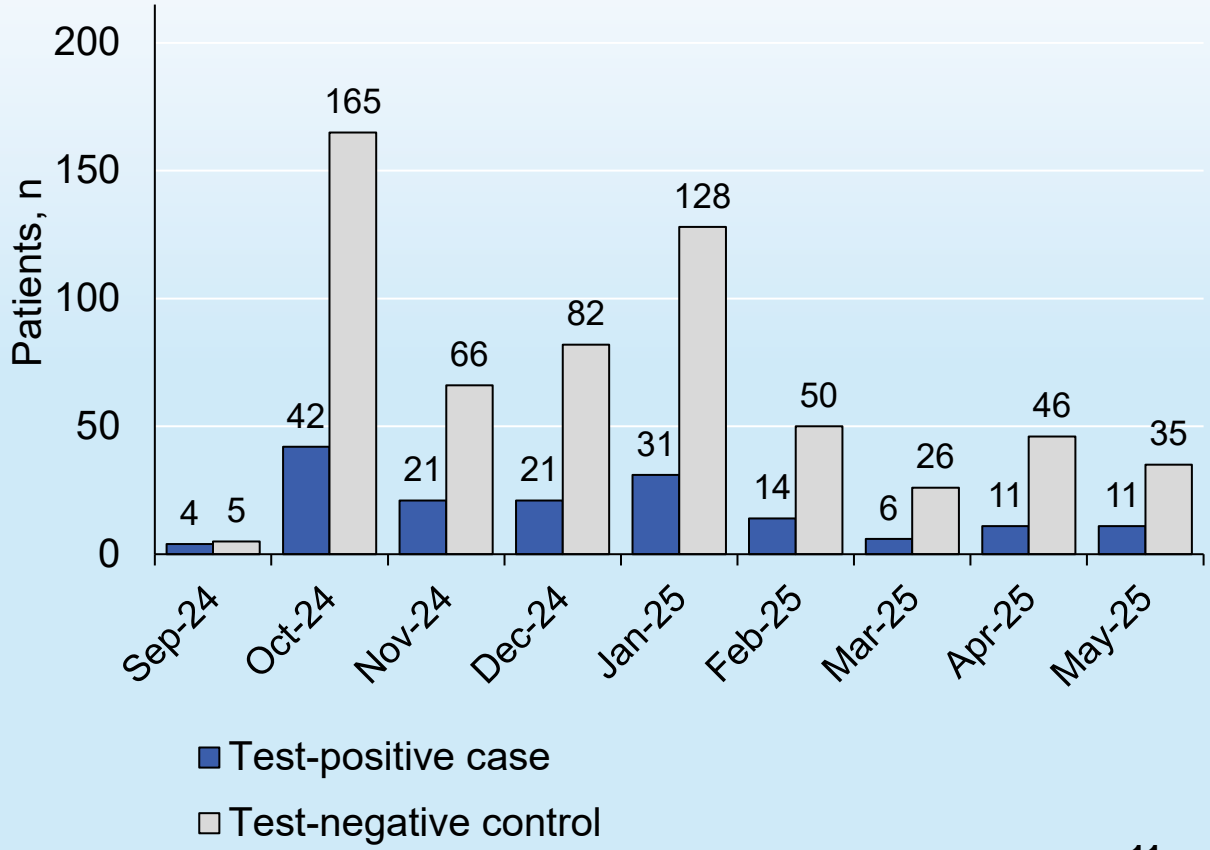


Table 1. Characteristics of patients in id.DRIVE hospitalized with severe acute respiratory illnesses according to BNT162b2 JN.1-adapted vaccine receipt and SARS-CoV-2 test status, Europe, 3 September 2024–31 May 2025

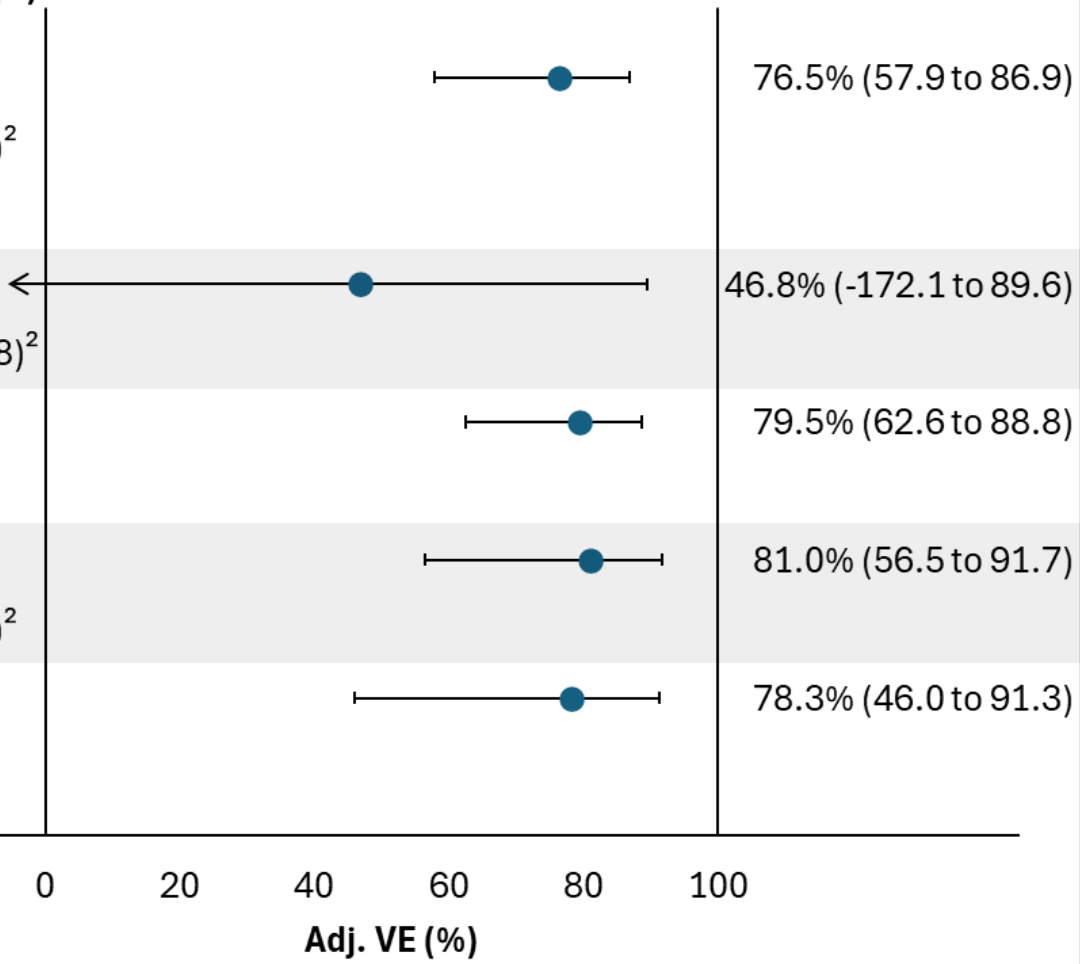
	Total, N (col %)	Received BNT162b2 JN.1-adapted vaccine in 2024–2025 season, N (col %)		Did not receive any COVID-19 vaccination in 2024–2025 season, N (col %)	
		Test-positive cases	Test-negative controls	Test-positive cases	Test-negative controls
Total	764	45	264	116	339
Sex					
Female	370 (48.4)	21 (46.7)	129 (48.9)	64 (55.2)	156 (46.0)
Male	394 (51.6)	24 (53.3)	135 (51.1)	52 (44.8)	183 (54.0)
Age, years – median (IQR)	77 (65–86)	87 (77–91)	83 (75–89)	76 (66.5–83.2)	68 (57–80.5)
Number of chronic conditions					
0–1	172 (22.5)	8 (17.8)	34 (12.9)	25 (21.6)	105 (31.0)
2	173 (22.6)	5 (11.1)	61 (23.1)	31 (26.7)	76 (22.4)
≥3	419 (54.8)	32 (71.1)	169 (64.0)	60 (51.7)	158 (46.6)

Table 1 (cont'd). Characteristics of patients in id.DRIVE hospitalized with severe acute respiratory illnesses according to BNT162b2 JN.1-adapted vaccine receipt and SARS-CoV-2 test status, Europe, 3 September 2024–31 May 2025

	Total, N (col %)	Received BNT162b2 JN.1-adapted vaccine in 2024–2025 season, N (col %)		Did not receive any COVID-19 vaccination in 2024–2025 season, N (col %)	
		Test-positive cases	Test-negative controls	Test-positive cases	Test-negative controls
Total	764	45	264	116	339
Chronic condition					
Asthma	66 (8.6)	3 (6.7)	19 (7.2)	6 (5.2)	38 (11.2)
Lung disease	285 (37.3)	10 (22.2)	105 (39.8)	41 (35.3)	129 (38.1)
Cardiovascular disease	329 (43.1)	26 (57.8)	140 (53.0)	50 (43.1)	113 (33.3)
Hypertension	466 (61.0)	35 (77.8)	192 (72.7)	68 (58.6)	171 (50.4)
Chronic kidney disease	157 (20.5)	17 (37.8)	54 (20.5)	27 (23.3)	59 (17.4)
Chronic liver disease	42 (5.5)	0 (0.0)	13 (4.9)	7 (6.0)	22 (6.5)
Type 1 diabetes	10 (1.3)	0 (0.0)	4 (1.5)	0 (0.0)	6 (1.8)
Type 2 diabetes	191 (25.0)	17 (37.8)	77 (29.2)	29 (25.0)	68 (20.1)
Neurological disorder	167 (21.9)	14 (31.1)	79 (29.9)	26 (22.4)	48 (14.2)
Immunodeficiency or cancer	168 (22.0)	15 (33.3)	44 (16.7)	31 (26.7)	78 (23.0)
Obesity	162 (21.2)	7 (15.6)	63 (23.9)	27 (23.3)	65 (19.2)

Figure 3. BNT162b2 JN.1-adapted adjusted vaccine effectiveness against COVID-19 hospitalization in Europe using id.DRIVE platform, 3 September 2024–31 May 2025

Strata	Exposure	Total, N	Test-positive cases, N (%)	Test-negative controls, N (%)	Days since last vaccine dose, median (IQR)	Adj. VE (95% CI)[1]
Overall	Yes	309	45 (15%)	264 (85%)	92 (66 to 157)	76.5% (57.9 to 86.9)
	No	455	116 (25%)	339 (75%)	716 (369 to 1066)[2]	
Age group (years)						
18–64y	Yes	25	5 (20%)	20 (80%)	71 (47 to 111)	46.8% (-172.1 to 89.6)
	No	160	28 (18%)	132 (82%)	1042 (770 to 1128)[2]	
≥65y	Yes	284	40 (14%)	244 (86%)	92 (69 to 159)	79.5% (62.6 to 88.8)
	No	295	88 (30%)	207 (70%)	477 (359 to 879)[2]	
65–79y	Yes	89	11 (12%)	78 (88%)	88 (65 to 144)	81.0% (56.5 to 91.7)
	No	158	43 (27%)	115 (73%)	522 (356 to 1020)[2]	
≥80y	Yes	195	29 (15%)	166 (85%)	95 (72 to 161)	78.3% (46.0 to 91.3)
	No	137	45 (33%)	92 (67%)	451 (361 to 788)[2]	



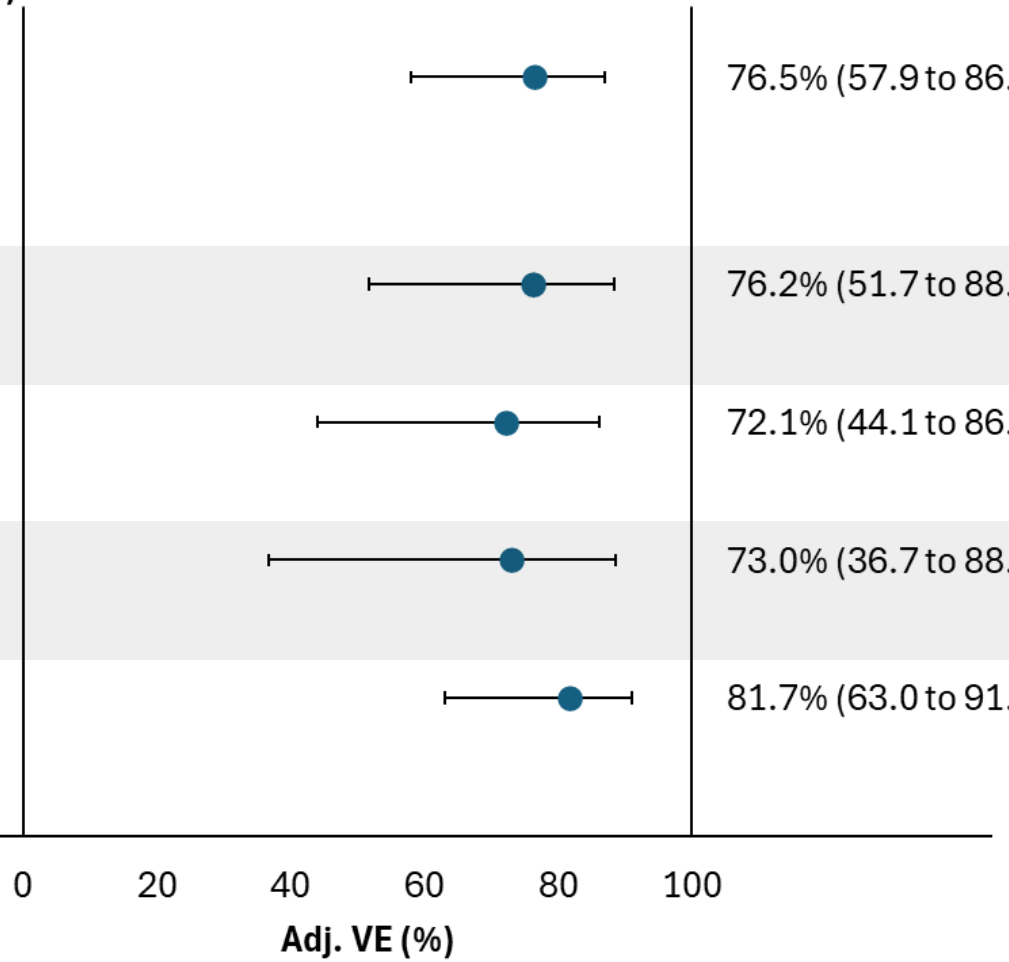
Adj., adjusted; CI, confidence interval; IQR, interquartile range; N, number; VE, vaccine effectiveness; y, years

1 VE estimates are adjusted for date of symptom onset, age, sex, number of chronic conditions and receipt of influenza vaccine in the 12 months prior to current hospital admission.

2 'Never vaccinated' patients were excluded when calculating the median (IQR) of time since last vaccine dose in the unexposed group (patients who did not receive any dose of a COVID-19 vaccine in the 2024–2025 autumn/winter season).

Figure 4. BNT162b2 JN.1-adapted adjusted vaccine effectiveness against COVID-19 hospitalization in Europe using id.DRIVE platform, 3 September 2024–31 May 2025

Strata	Exposure	Total, N	Test-positive cases, N (%)	Test-negative controls, N (%)	Days since last vaccine dose, median (IQR)	Adj. VE (95% CI)[1]
Overall	Yes	309	45 (15%)	264 (85%)	92 (66 to 157)	76.5% (57.9 to 86.9)
	No	455	116 (25%)	339 (75%)	716 (369 to 1066)[2]	
Weeks since JN.1-adapted vaccine dose						
2 to <12	Yes	133	19 (14%)	114 (86%)	63 (46 to 74)	76.2% (51.7 to 88.3)
	No	455	116 (25%)	339 (75%)	716 (369 to 1066)[2]	
12 to <18	Yes	73	12 (16%)	61 (84%)	99 (91 to 111)	72.1% (44.1 to 86.1)
	No	455	116 (25%)	339 (75%)	716 (369 to 1066)[2]	
18 to <24	Yes	41	7 (17%)	34 (83%)	154 (140 to 161)	73.0% (36.7 to 88.5)
	No	455	116 (25%)	339 (75%)	716 (369 to 1066)[2]	
24 to <32.5	Yes	62	7 (11%)	55 (89%)	190 (180 to 202)	81.7% (63.0 to 91.0)
	No	455	116 (25%)	339 (75%)	716 (369 to 1066)[2]	



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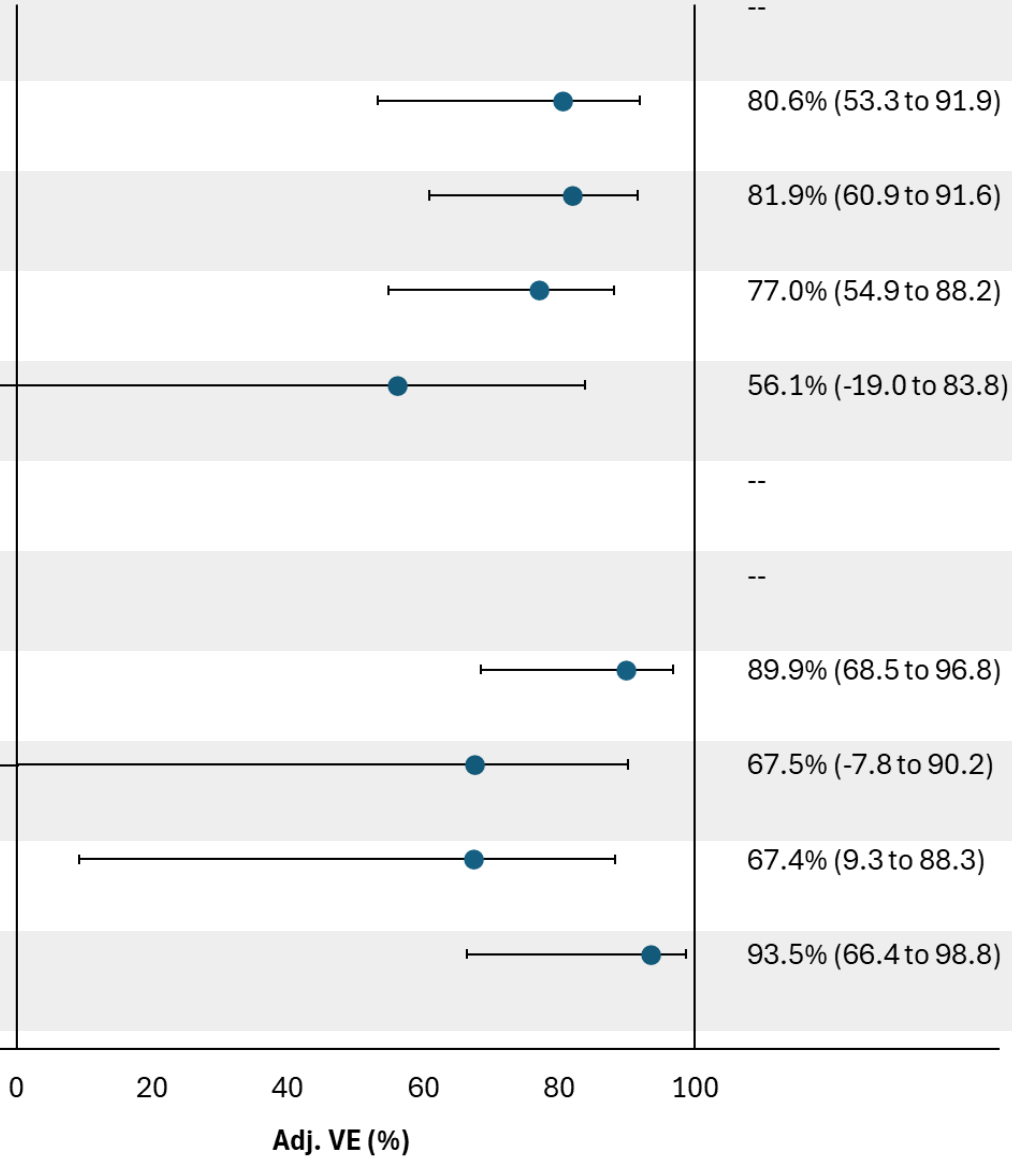
1 VE estimates are adjusted for date of symptom onset, age, sex, number of chronic conditions and receipt of influenza vaccine in the 12 months prior to current hospital admission.

2 'Never vaccinated' patients were excluded when calculating the median (IQR) of time since last vaccine dose in the unexposed group (patients who did not receive any dose of a COVID-19 vaccine in the 2024–2025 autumn/winter season).

Figure 5. BNT162b2 JN.1-adapted adjusted vaccine effectiveness against COVID-19 hospitalization in Europe using id.DRIVE platform, 3 September 2024–31 May 2025

Strata	Exposure	Total, N	Test-positive cases, N (%)	Test-negative controls, N (%)	Days since last vaccine dose, median (IQR)	Adj. VE (95% CI)[1]
Asthma	Yes	22	3 (14%)	19 (86%)	83 (60 to 174)	--
	No	44	6 (14%)	38 (86%)	853 (486 to 1075)[2]	
Lung disease	Yes	115	10 (9%)	105 (91%)	93 (66 to 164)	80.6% (53.3 to 91.9)
	No	170	41 (24%)	129 (76%)	468 (357 to 1020)[2]	
Cardiovascular disease	Yes	166	26 (16%)	140 (84%)	92 (65 to 156)	81.9% (60.9 to 91.6)
	No	163	50 (31%)	113 (69%)	446 (358 to 925)[2]	
Hypertension	Yes	227	35 (15%)	192 (85%)	91 (69 to 159)	77.0% (54.9 to 88.2)
	No	239	68 (28%)	171 (72%)	544 (359 to 991)[2]	
Chronic kidney disease	Yes	71	17 (24%)	54 (76%)	92 (68 to 144)	56.1% (-19.0 to 83.8)
	No	86	27 (31%)	59 (69%)	646 (361 to 1040)[2]	
Chronic liver disease	Yes	13	0 (0%)	13 (100%)	74 (47 to 93)	--
	No	29	7 (24%)	22 (76%)	737 (367 to 1120)[2]	
Type 1 diabetes	Yes	4	0 (0%)	4 (100%)	72 (58 to 95)	--
	No	6	0 (0%)	6 (100%)	846 (490 to 992)[2]	
Type 2 diabetes	Yes	94	17 (18%)	77 (82%)	92 (71 to 163)	89.9% (68.5 to 96.8)
	No	97	29 (30%)	68 (70%)	567 (363 to 1022)[2]	
Neurological disorder	Yes	93	14 (15%)	79 (85%)	93 (72 to 161)	67.5% (-7.8 to 90.2)
	No	74	26 (35%)	48 (65%)	552 (362 to 994)[2]	
Immunodeficiency or cancer[3]	Yes	59	15 (25%)	44 (75%)	90 (64 to 132)	67.4% (9.3 to 88.3)
	No	109	31 (28%)	78 (72%)	709 (368 to 1065)[2]	
Obesity	Yes	71	8 (11%)	63 (89%)	95 (70 to 172)	93.5% (66.4 to 98.8)
	No	94	27 (29%)	67 (71%)	683 (357 to 1020)[2]	



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1 VE estimates are adjusted for date of symptom onset, age, sex, number of chronic conditions and receipt of influenza vaccine in the 12 months prior to current hospital admission.
2 'Never vaccinated' patients were excluded when calculating the median (IQR) of time since last vaccine dose in the unexposed group (patients who did not receive any dose of a COVID-19 vaccine in the 2024–2025 autumn/winter season).
3 The categories 'Cancer' and 'Immunodeficiency' are counted as separate conditions. Here, the VE estimate among patients with 'Immunodeficiency or cancer' is provided as a composite.

Conclusions

BNT162b2 JN.1-adapted vaccine:

- Effective against hospitalization in older adults and in patients with high-risk conditions for severe COVID-19
- Provided durable protection lasting through at least 6 months

Findings support clinical benefit of BNT162b2 among patients at high-risk for severe outcomes of COVID-19

Continued importance of COVID-19 vaccination in high-risk patients

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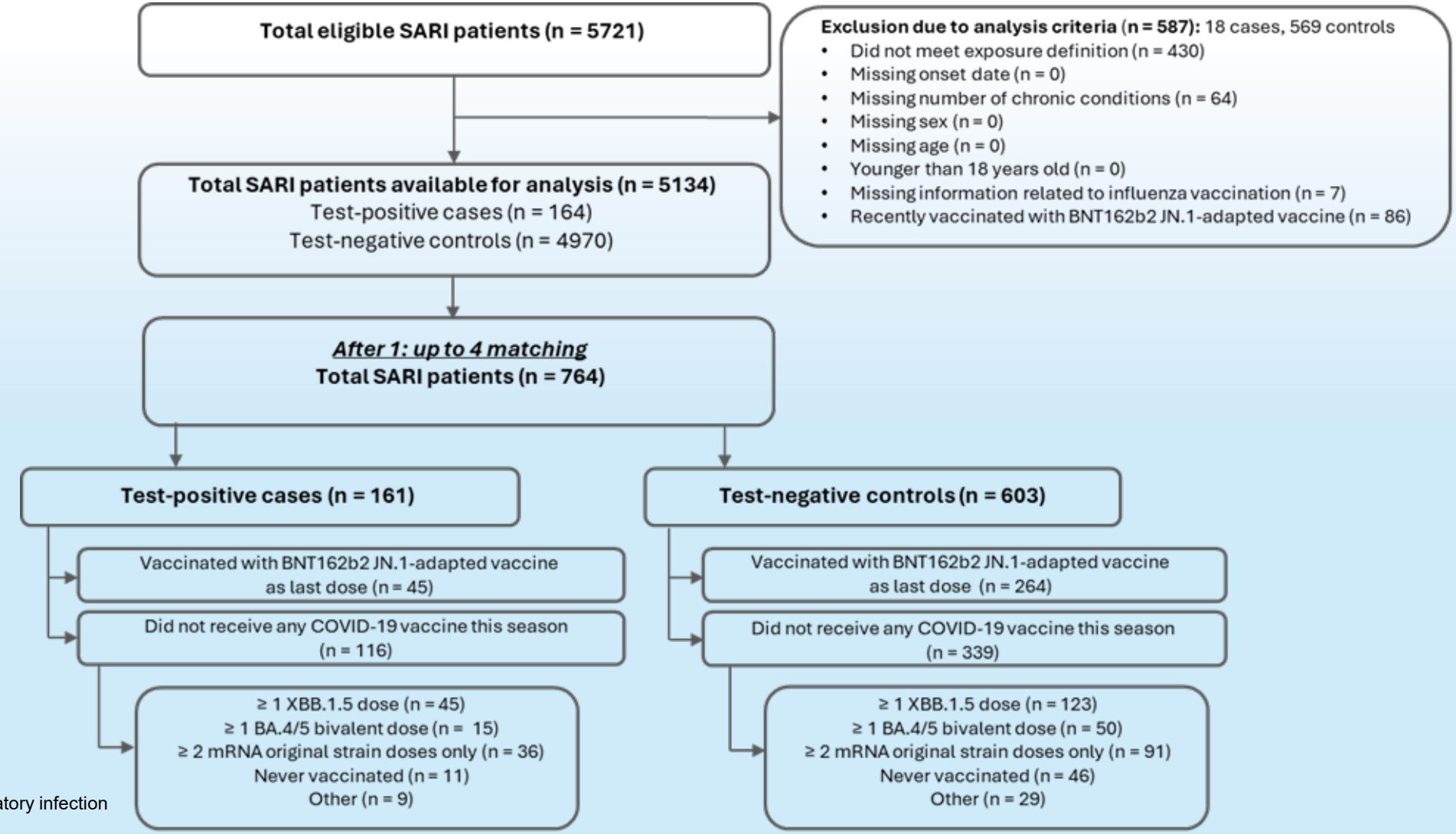
Supporting slides

Figure 6: BNT162b2 JN.1-adapted vaccine effectiveness against COVID-19 hospitalization in Europe, 3 September 2024–31 May 2025: Attrition diagram of id.DRIVE study population



SARI: severe acute respiratory infection

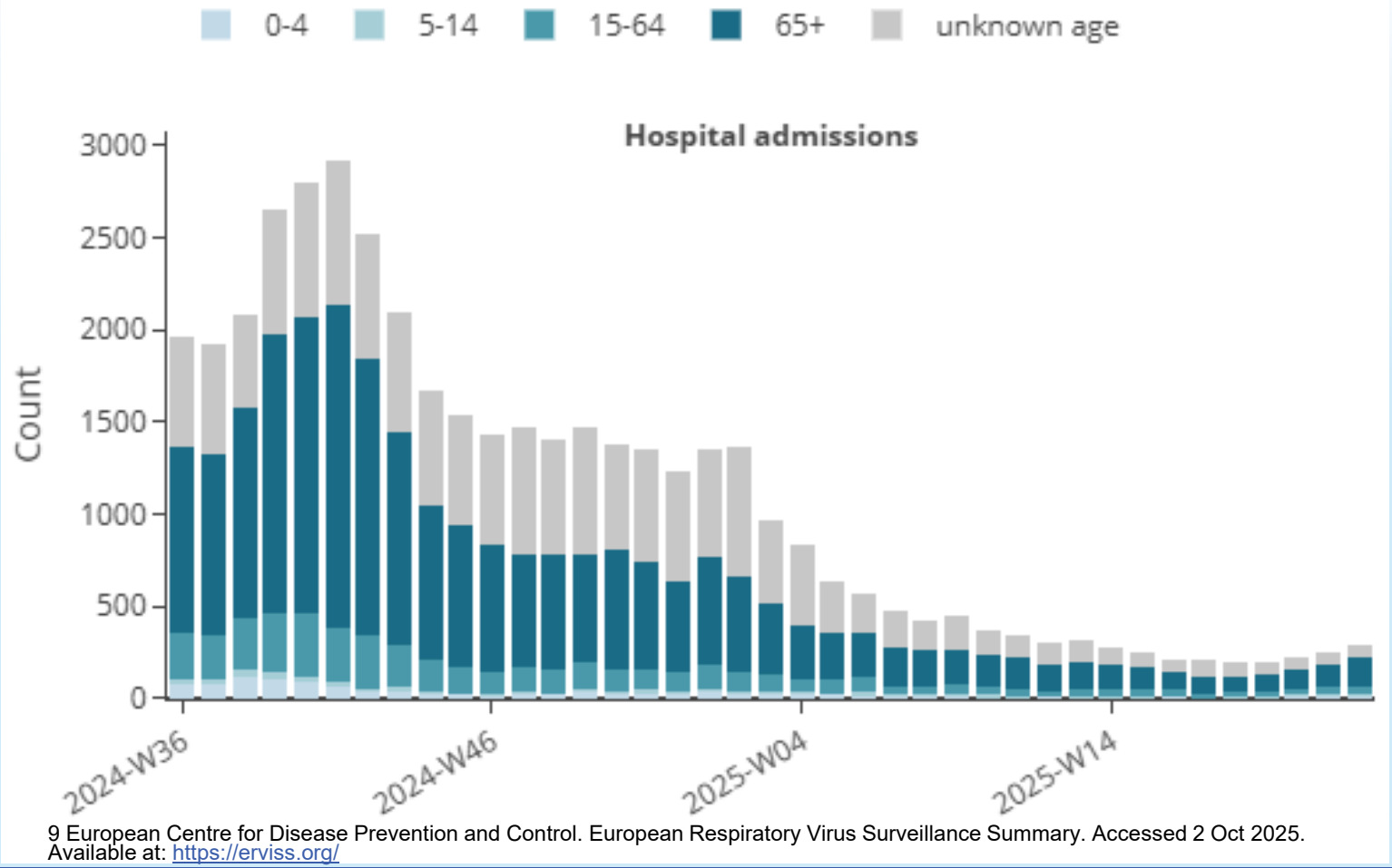
Table 1 (cont'd). Characteristics of patients in id.DRIVE hospitalized with severe acute respiratory illnesses according to BNT162b2 JN.1-adapted vaccine receipt and SARS-CoV-2 test status, Europe, 3 September 2024–31 May 2025

	Total, N (col %)	Received BNT162b2 JN.1-adapted vaccine in 2024–2025 season, N (col %)		Did not receive any COVID-19 vaccination in 2024–2025 season, N (col %)	
		Test-positive cases	Test-negative controls	Test-positive cases	Test-negative controls
Total	764	45	264	116	339
Prior vaccination*					
Never vaccinated	57 (7.5)	0 (0.0)	0 (0.0)	11 (9.5)	46 (13.6)
≥2 mRNA wildtype doses only	127 (16.6)	0 (0.0)	0 (0.0)	36 (31.0)	91 (26.8)
≥1 mRNA BA.4/5 dose	102 (13.4)	*Suppressed*	35 (13.3)	15 (12.9)	50 (14.7)
≥1 XBB.1.5 dose	429 (56.2)	39 (86.7)	222 (84.1)	45 (38.8)	123 (36.3)

*Does not include vaccination regimens with vaccines not mentioned here (n=49 total)

2024–2025 Season Epidemiologic Context

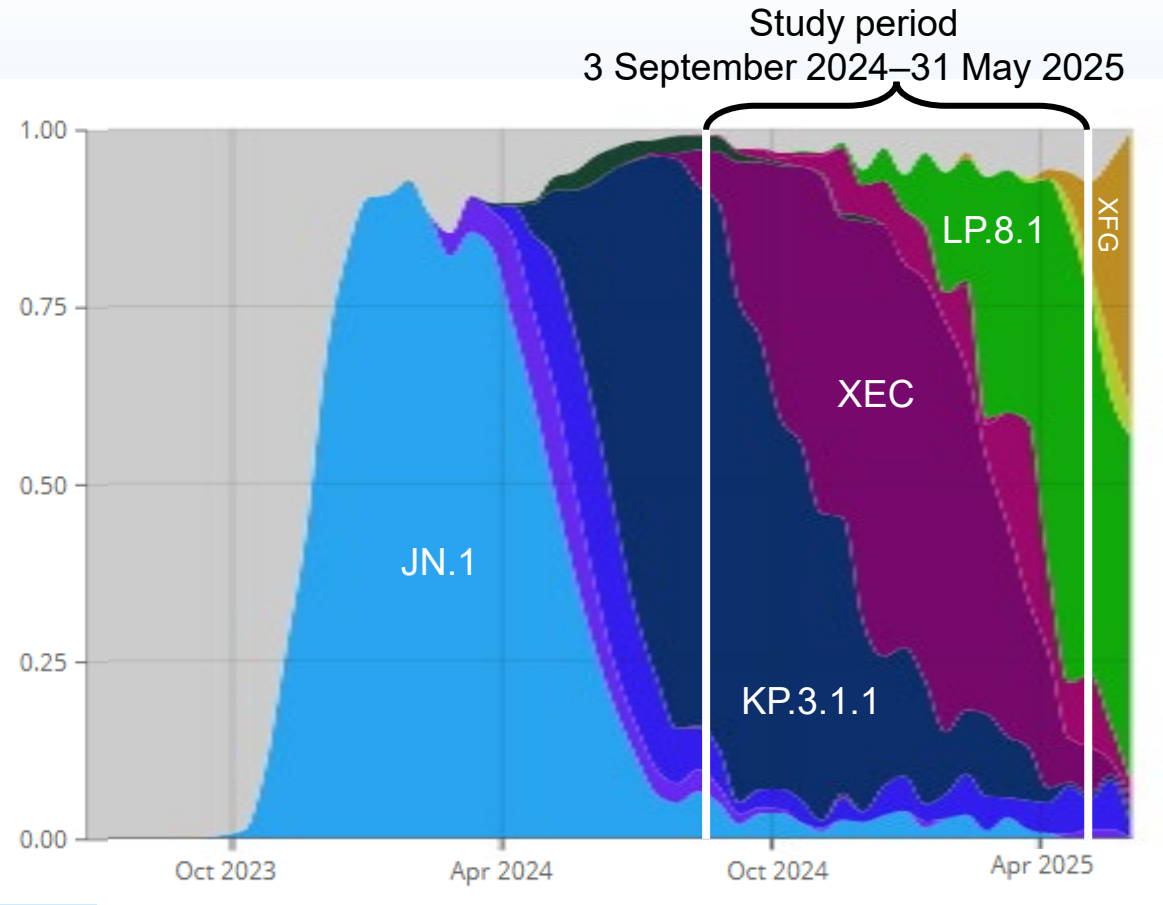
Aggregate weekly laboratory-confirmed hospitalized SARS-CoV-2 cases in Europe, 2 September 2024–1 Jun 2025[9]



9 European Centre for Disease Prevention and Control. European Respiratory Virus Surveillance Summary. Accessed 2 Oct 2025. Available at: https://erviss.org/

2024–2025 Season Epidemiologic Context

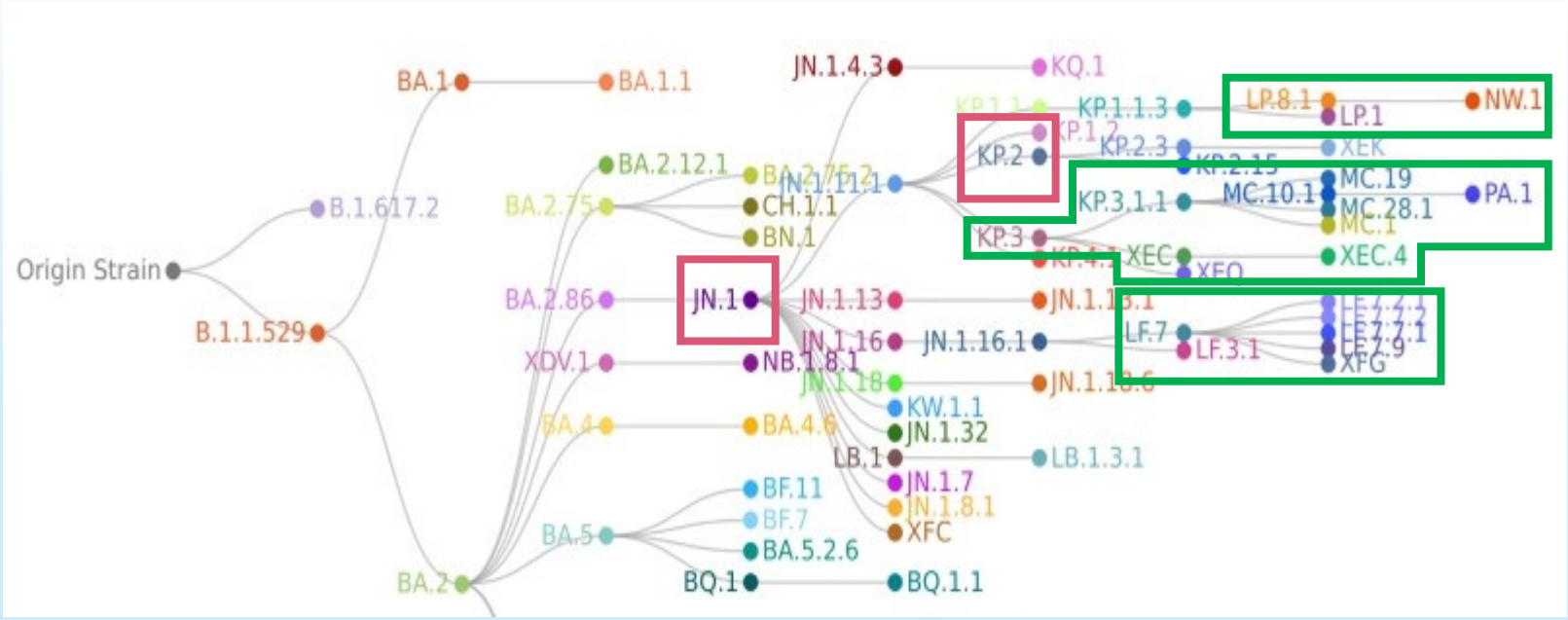
Circulating SARS-CoV-2 variants, Spain, October 2023–June 2025[10]



10 Hodcroft EB. CoVariants: SARS-CoV-2 Mutations and Variants of Interest. Accessed 2 Oct 2025. Available at: https://covariants.org/

2024–2025 Season Epidemiologic Context

Phylogenetic tree of SARS-CoV-2 Pango lineages[11]



2024–2025 vaccine targets

Main circulating SARS-CoV-2 variants, Spain, 3 September 2024–31May 2025

11 Centers for Disease Control and Prevention. COVID-19 Variants and Genomic Surveillance. Accessed 2 Oct 2025. Available at: https://www.cdc.gov/covid/php/variants/variants-and-genomic-surveillance.html