Rapid communication

Effectiveness of influenza vaccines in children aged 6 to 59 months: a test-negative case–control study at primary care and hospital level, Spain 2023/24

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Citation style for this article:
Pérez-Gimeno Gloria, Mazagatos Clara, Lorusso Nicola, Basile Luca, Martínez-Pino Isabel, Corpas Burgos Francisca, Batalla Rebolla Noa, Rumayor Zarzuelo Mercedes B, Andreu Ivorra Blanca, Giménez Duran Jaume, Castrillejo Daniel, Guiu Cañete Inés, Huerta Huerta Marta, García Becerril Marta, Ramos Marín Violeta, Casas Inmaculada, Pozo Francisco, Monge Susana, the SiVIRA group. Effectiveness of influenza vaccines in children aged 6 to 59 months: a test-negative case–control study at primary care and hospital level, Spain 2023/24. Euro Surveill. 2024;29(40):pii=2400618. https://doi.org/10.2807/1560-7917.ES.2024.29.40.2400618

Article received on 19 Sept 2024 / Accepted on 03 Oct 2024 / Published on 03 Oct 2024

During 2023/24, all children aged 6 to 59 months were targeted for seasonal influenza vaccination in Spain nationally. Using a test-negative case–control design with sentinel surveillance data, we estimated adjusted influenza vaccine effectiveness (IVE) against any influenza type to be 70% (95% confidence interval (CI): 51 to 81%) for primary care patients with acute respiratory illness (ARI) and 77% (95% CI: 21 to 93%) for hospitalised patients with severe ARI. In primary care, where most subtyped viruses (61%; 145/237) were A(H1N1), adjusted IVE was 77% (95% CI: 56 to 88%) against A(H1N1)pdm09.

It is estimated that globally, 109 million influenza virus infections occur annually in 0 to 59-month-old children [1]; in this age group, infection can lead to severe disease. In Spain, children under 5 years of age have the second highest rate of hospitalisation admission due to influenza, only below that of people 65 years or older [2]. Moreover, it has been reported that children play key roles in the community circulation of the virus and in the amplification of influenza epidemics [3]. Influenza vaccination in Spain was recommended in the 2023/24 season, for the first time at national level, to all children aged 6 to 59 months [4].

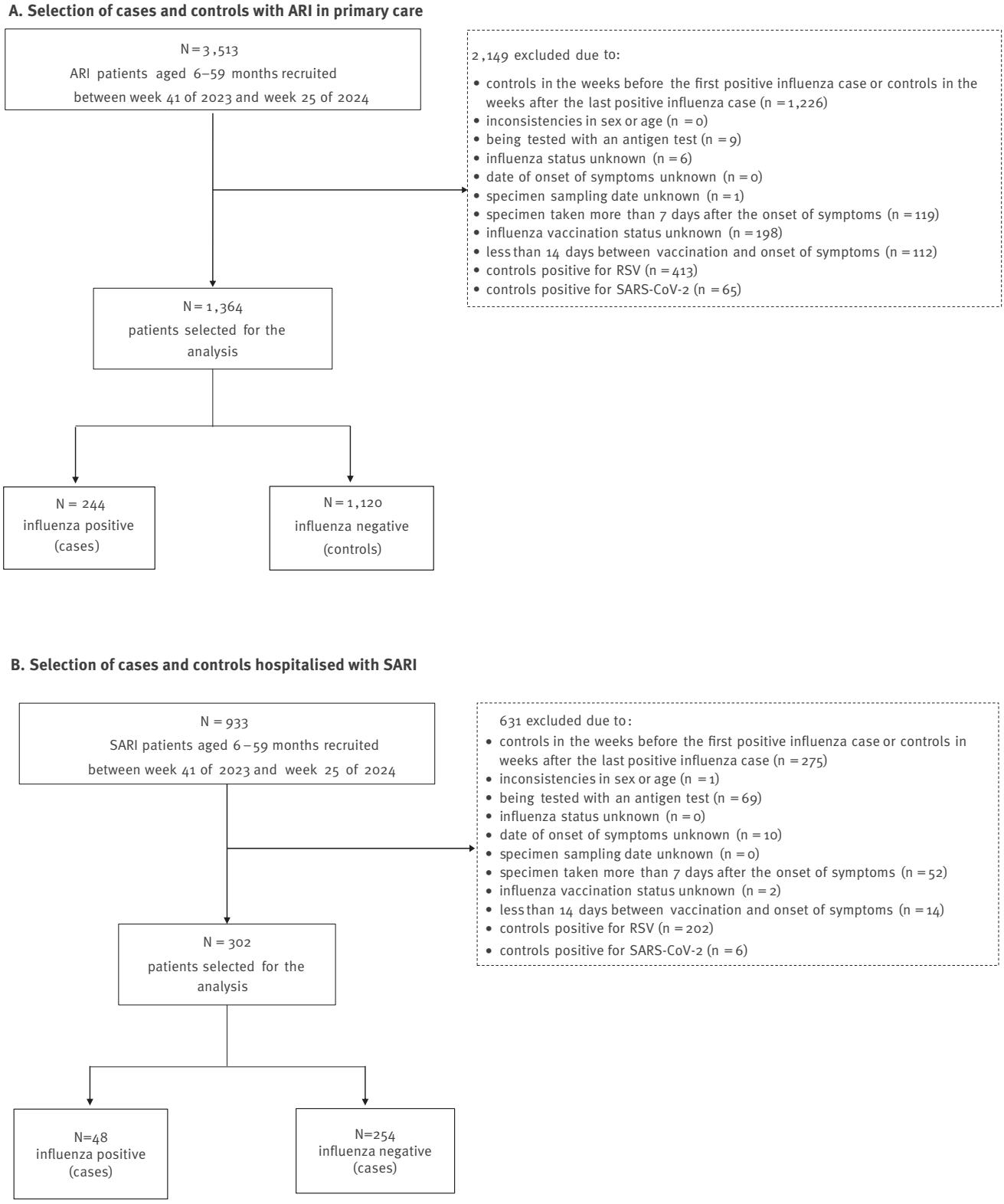
For children aged 6 to 59 months during the 2023/24 season, we estimated influenza vaccine effectiveness (IVE) against acute respiratory infections (ARI) in those attending primary care (PC), or against severe ARI (SARI) in those hospitalised, overall and by influenza virus type, subtype, and clade.

Study setting

In Spain, the 2023/24 season was characterised by the circulation of influenza A. In both PC and hospitals, the A(H1N1)pdm09 subtype was predominant, followed by A(H3N2), while influenza B was scarcely detected. The children vaccination campaign started on week 39 2023 with one dose of tetravalent vaccines, inactivated (Influvac Tetra, Vaxigrip Tetra, Flucelvax Tetra, and Fluarix Tetra) or intranasal live attenuated egg-based (Fluenz Tetra) [4], which was provided free of charge at PC. The national vaccination coverage was 31.16% [5].

Figure 1

Flowchart of selection of paediatric cases and controls[a] eligible for the sentinel surveillance, to estimate vaccine effectiveness against influenza virus-caused A) acute respiratory infections (ARI) in primary care and B) severe ARI (SARI) in inpatients, Spain, September 2023–June 2024 (n = 27 hospitals in 12 regions)

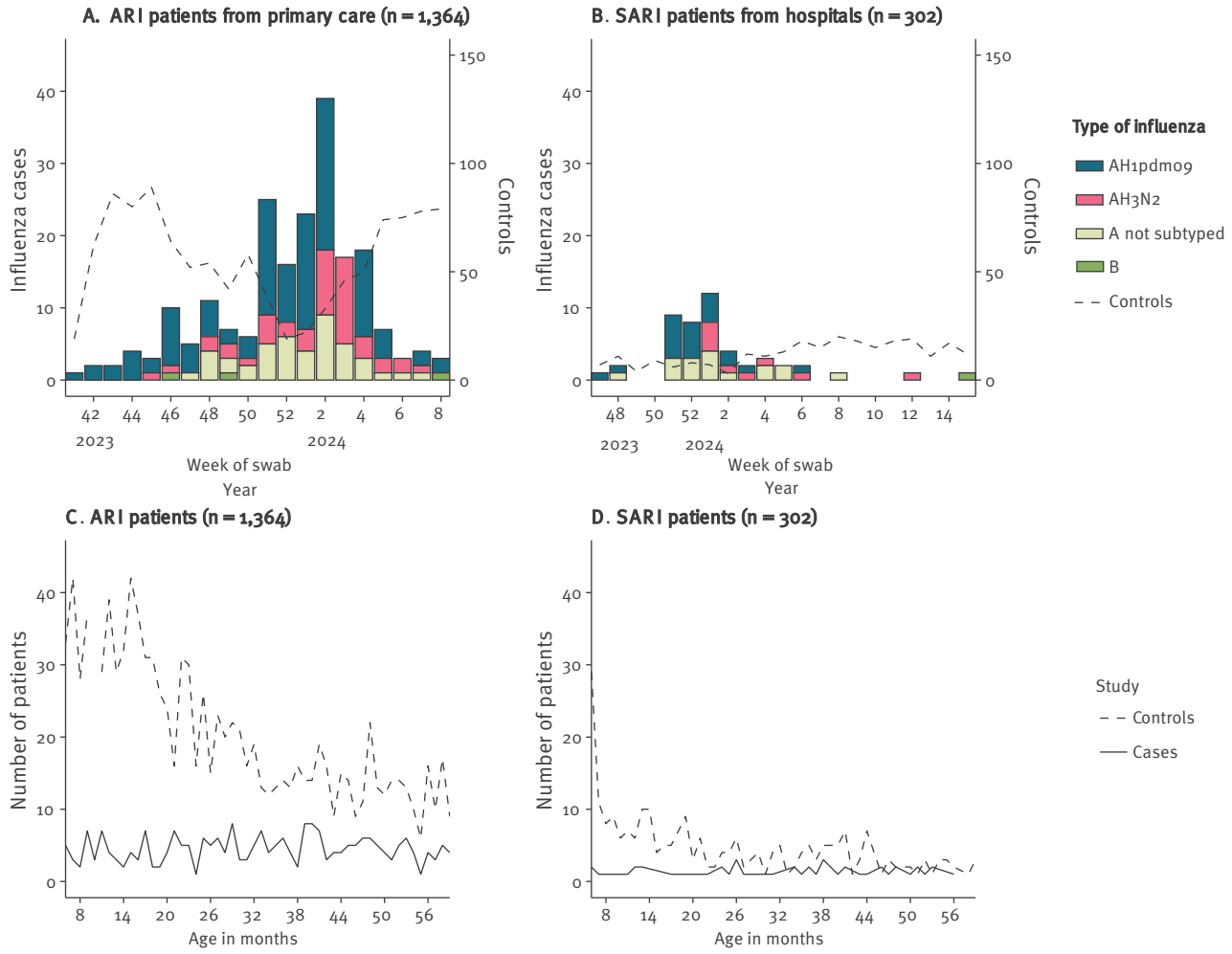


ARI: acute respiratory symptoms; RSV: respiratory syncytial virus; SARI: severe ARI; SARS-CoV-2: severe acute respiratory coronavirus 2.

[a] Children aged 6–59 months.

Figure 2

Number of paediatric cases and controls[a] selected in the study by week and type/subtype of influenza among A) patients from primary care with acute respiratory infections (ARI), and B) hospitalised patients with severe ARI (SARI), and by age in months among C) ARI and D) SARI, Spain, September 2023–June 2024 (n = 27 hospitals in 12 regions)



ARI: acute respiratory symptoms; SARI: severe ARI.

[a] Children aged 6–59 months.

Data sources, study design and eligibility criteria

The Surveillance System of Acute Respiratory Infections in Spain (SiVIRA) monitors ARI at PC level and SARI at hospital level. ARI is defined as sudden onset of at least one symptom among cough, sore throat, shortness of breath and/or rhinorrhoea (with or without fever ≥ 38°C) and a clinician's judgment that the illness is due to an infection. SARI is an ARI that required hospitalisation for ≥ 24 hours [6,7]. Physicians systematically select for swabbing (and reverse-transcription (RT)-PCR virological testing) the first two to five ARI patients each week at PC and all patients hospitalised with SARI on pre-defined weekdays (Tuesdays and/or Wednesdays). Clinical, epidemiological, vaccination and virological data are also collected. Specimens testing positive for influenza are recommended to be typed and subtyped. National Influenza Centres and the National Centre of Microbiology sequenced the influenza viruses.

We conducted a test-negative case–control study, using SiVIRA data from 12 of 19 regions in Spain and 27 hospitals. We included all children aged 6–59 months who attended PC with ARI or were hospitalised with SARI between week 41 2023 (14 days after onset of vaccination campaign) and week 25 2024, had a specimen collected within 7 days of symptoms onset, and had a valid RT-PCR result for influenza. Full selection criteria are outlined in Figure 1. Participants were classified as cases if they tested positive and as controls if they tested negative. Influenza vaccination data were collected from regional vaccination records, and vaccinations administered at least 14 days before symptoms onset were considered.

Patients' characteristics

We included 1,364 ARI patients in PC (244 cases), and 302 SARI patients in hospitals (48 cases). In both settings, controls were younger ($p < 0.001$), and in the PC

Table 1

Characteristics of acute respiratory infection and severe acute respiratory infection paediatric influenza cases and controls aged 6 to 59 months selected into the study, Spain, September 2023–June 2024 (n = 27 hospitals in 12 regions)

Characteristic	ARI patients (n = 1,364)							SARI patients (n = 302)						
	Cases (n = 244)			Controls (n = 1,120)			p[a]	Cases (n = 48)			Controls (n = 254)			p[a]
Descriptive statistic	Median		IQR	Median		IQR	p	Median		IQR	Median		IQR	p
Age in months	33		21–45	23		13–38	0.000	34.5		18.5–41	19		10–38	0.000
Descriptive statistic	n	Denom.[b]	%	n	Denom.[b]	%	p	n	Denom.[b]	%	n	Denom.[b]	%	p
Sex[c]														
Female	107	244	43.9	523	1,120	46.7	0.419	20	48	41.7	113	254	44.5	0.651
Male	137	244	56.1	597	1,120	53.3		28	48	58.3	141	254	55.5	
Presence of chronic condition														
One or more	8	171	4.7	62	839	7.4	0.094	11	42	26.2	59	190	31.1	0.556
Hypertension	0	168	0	0	840	0	NA	0	47	0	1	237	0.4	0.696
Chronic cardiovascular disease	0	168	0	4	842	0.5	0.387	2	48	4.2	10	239	4.2	0.668
Chronic respiratory disease	6	182	3.3	56	900	6.2	0.088	6	48	12.5	35	235	14.9	0.510
Diabetes	0	168	0	0	842	0	NA	0	43	0	5	221	2.3	0.383
Chronic liver disease	0	168	0	1	843	0.1	0.666	0	47	0	0	230	0	NA
Chronic kidney disease	0	168	0	0	842	0	0	1	43	2.3	3	221	1.4	0.501
Immunodeficiencies	1	168	0.6	2	842	0.2	0.401	0	44	0	3	185	1.6	0.455
Other chronic disease	1	168	0.6	0	836	0	0.000	3	45	6.7	27	201	13.4	0.426
Seasonal influenza vaccination														
Yes	59	244	24.2	394	1,120	35.2	0.001	8	48	16.7	92	254	36.2	0.081
Influenza type (subtype)														
A(H1N1)	145	237	61.2	NA	NA	NA	NA	21	48	43.8	NA	NA	NA	NA
A(H3N2)	45	237	19.0	NA	NA	NA	NA	9	48	18.8	NA	NA	NA	NA
A (unsubtyped)	44	237	18.6	NA	NA	NA	NA	17	48	35.4	NA	NA	NA	NA
B	3	237	1.3	NA	NA	NA	NA	1	48	2.1	NA	NA	NA	NA

ARI: acute respiratory infection; denom.: denominator; IQR: interquartile range; NA: not applicable; SARI: severe ARI.

[a] Pearson's chi-square test.

[b] Denominators include the number of cases with available information on the characteristic in question.

[c] Data on sex were collected as male, female and not reported.

setting, controls had higher influenza vaccination coverage (p = 0.001). In both settings, influenza B exhibited low circulation (Figure 2, Table 1). For influenza A viruses that were subtyped, A(H1N1)pdm09 dominated (61.2% and 43.8% in PC and hospitals, respectively), followed by A(H3N2) (19% and 18.8% respectively).

Vaccine effectiveness

The odds of being vaccinated was compared between influenza cases and controls through an odds ratio (OR) and its 95% confidence interval (95% CI) using logistic regression and a penalised logistic method (Firth's method) when the number of cases vaccinated was less than 10 [8].

Estimates were adjusted for potential confounders including sex, age in months, epidemiological week, presence of chronic conditions, and region or hospital for ARI or SARI models, respectively; IVE = (1 – OR) × 100. IVE was estimated by type/subtype/clade when the sample size allowed, and only considering the weeks with positive cases for the respective type/subtype/clade.

Among ARI patients in PC, IVE against any influenza infection was 70% (95% CI: 51 to 81) (Table 2). IVE was 77% (95% CI: 56 to 88) against A(H1N1)pdm09, which circulated predominately (61%), and higher against clade 5a.2a at 96% (95% CI: 23 to 100), while no protection could be demonstrated against A(H3N2) or other clades, possibly related to the low number of cases and the extremely wide CIs. Among hospitalised SARI patients, the point estimate was 77% (95% CI: 21 to 93) against any influenza, and the estimated IVE by subtype had very low precision, with CIs including the null.

Table 2

Crude and adjusted influenza vaccine effectiveness with 95% CI against acute respiratory infections (ARI) in primary care and severe ARI (SARI) in hospitals for patients aged 6 to 59 months, overall, by type/subtype, and by clade of influenza virus, Spain, September 2023–June 2024 (n = 27 hospitals in 12 regions)

Setting and influenza type subtype or clade		Cases vaccinated/ total cases	Controls vaccinated/ total controls[a]	Crude IVE (%)	95% CI	Adjusted IVE (%)[b]	95% CI
Primary care consultation with ARI							
Main analysis	Any influenza	59/244	394/1,120	41	19 to 57	70	51 to 81
	A(H1N1)pdm09	30/145	394/1,120	52	27 to 68	77	56 to 88
	A(H3N2)	20/44	333/705	7	−72 to 49	18	−97 to 65
	B	0/3	371/784	NA	NA	NA	NA
Clade-specific analysis	5a.2a (H1N1)	3/22	221/814	58	−45 to 88	96	23 to 100
	5a.2a.1 (H1N1)	3/11	221/733	13	−231 to 77	49	−184 to 91
	2a.3a.1 (H3N2)	9/12	288/535	−157	−861 to 31	−116	−824 to 50
Hospitalisation due to SARI							
Any influenza		8/48	92/254	65	22 to 84	77	21 to 93
A(H1N1)pdm09		3/21	44/109	75	11 to 93	75	−68 to 96
A(H3N2)		4/9	67/169	−22	−370 to 68	−3	−563 to 84
B		0/1	4/12	NA	NA	NA	NA

ARI: acute respiratory infection; CI: confidence interval; IVE: influenza vaccine effectiveness; NA: not applicable as the number of cases vaccinated was insufficient to perform estimates; SARI: severe ARI.

[a] Controls were excluded in weeks with no circulation of the specific influenza subtype or clade.

[b] Logistic regression adjusted by sex, age in months (as restricted cubic spline), epidemiological week (as restricted cubic spline), region and presence of chronic conditions.

Clade analyses could not be performed among hospitalised patients.

Two sensitivity analyses were conducted. First, including controls positive for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and/or respiratory syncytial virus (RSV) changed estimates: in PC, to 68% (95% CI: 49 to 79) against overall influenza, 76% (95% CI: 55 to 87) against A(H1N1)pdm09 and 2% (95% CI: −130 to 58) against A(H3N2), and in hospitals to 76% (95% CI: 26 to 92), 78% (95% CI: −25 to 96) and 19% (95% CI: −374 to 86), respectively. Second, categorising unknown vaccination status as unvaccinated only changed IVE estimate in hospitals to 86% (95% CI: 39 to 97) against overall influenza, 76% (95% CI: −65 to 96) against A(H1N1)pdm09 and −7% (95% CI: −609 to 84) against A(H3N2).

Discussion

We found high IVE in children aged 6–59 months against influenza attended in PC, particularly against A(H1N1)pdm09 and clade 5a.2a, but we lacked sufficient sample size to provide accurate estimates of IVE against other subtypes and clades.

Despite the differences in the target age groups, our results are comparable with those of an interim 2023/24 investigation in children under 17 years, which found an overall similar IVE of 71% through the European PC multicentre study, and slightly higher IVE of 53% through the hospital multicentre study [9]. Early IVE estimates from Canada for A(H1N1) in children aged 6 months to 9 years both hospitalised and not hospitalised (74%), were also similar to ours [10]. The United States interim 2023/24 study, however, reported lower IVEs, ranging from 59% to 67% in outpatients below 17 years old in PC and ranging from 52% to 61% in hospitalised children aged 6 months to 17 years [11].

Our results indicated lower effectiveness against clade 5a.2a.1, although with very low precision and a 95% CI including the null. This is compatible with last season antigenic human studies, that had motivated World Health Organization (WHO) to change the 2023/24 vaccine clade recommendation from 5a.2a to 5a.2a.1 [12]. Skowronski et al. suggested that a mutation in the 2023/24 clade 5a.2a.1 vaccine high-growth reassortant, specifically the R142K(Ca2) reversion, may be responsible for reduced IVE [13]. This mutation affected only the high-growth reassortant IVR-238 used for egg-based vaccines, so comparing IVE between different vaccine brands against the same clade could provide more information. Unfortunately, we could not test this hypothesis.

Our study has other limitations inherent to observational studies and unmeasured confounders.

Conclusion

In conclusion, our results along with previously available evidence supports the effectiveness of influenza vaccination in children aged 6–59 months to prevent both influenza infection and hospitalisation. Continued

efforts are needed to increase coverage of influenza vaccination in this age group in future seasons.

Ethical statement

All data used for this study were collected as routine surveillance, and informed consent or official ethical approval was not required, as regulated by Royal Decree 2210/1995 of December 28 provided by the Ministry of Health and Consumer Affairs. Although individual informed consent was not required, all data were pseudo anonymised to protect patient privacy and confidentiality.

Funding statement

Some Autonomous Communities received funding from ECDC for the implementation of sentinel surveillance in Spain. Researchers at the National Centre of Epidemiology (Institute of Heath Carlos III) received funding from ECDC through the project "ECDC primary care network for Vaccine Effectiveness, Burden and Impact Studies and for Surveillance of Acute Respiratory Infections" Framework Contract nº ECDC/2021/019 and "ECDC Hospital network for Vaccine Effectiveness, Burden and Impact Studies and for Surveillance of Severe Acute Respiratory Infections" Framework Contract nº ECDC/2021/016 within the "Vaccine Effectiveness, Burden and Impact Studies (VEBIS) of COVID-19 and Influenza" platform.

Use of artificial intelligence tools

None declared.

Data availability

The National Centre of Epidemiology has the mandate to collect, analyse, and disseminate surveillance data on infectious diseases in Spain. There is no direct access to the SiVIRA database, but data used for this study are available upon request to the corresponding author.

Acknowledgements

We are very grateful to all participants in the SiVIRA group network, who have contributed to this work.

Conflict of interest

None declared.

Authors' contributions

G.P-G, C.M and S.M conceptualised the study, G.P-G performed the data analysis and the study results with inputs from C.M and S.M. G.P-G, C.M and S.M wrote the manuscript draft in collaboration. Members of the SiVIRA group contributed to the design and implementation of the surveillance system, including data collection, data curation, epidemiological analyses and interpretation. G.P-G,C.M, N.L, L.B, I.M-P, F.C.B, N.B.R, M.R.Z, B.A.I, J.G.D, D.C, I.G.C, M.H.H, M.G.B, V.R.M, I.C, F.P and S.M critically reviewed the manuscript and approved the final version.

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