Effectiveness of cell culture-based inactivated influenza vaccine against medically-attended, laboratory-confirmed influenza in Wisconsin, US, 2023-2024

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Background

- Cell culture-based inactivated influenza vaccine (ccIIV4) was developed because of concerns with egg-induced mutations in vaccine viruses.
- In 2022-23, approved age indication for ccIIV4 in the US was expanded to all children aged ≥6 months.
- There is limited real-world data on ccIIV4 effectiveness, particularly in young children.

Objective

- Estimate ccIIV4 effectiveness in Wisconsin using the test-negative design during the 2023-24 influenza season.

Methods

Recruitment

- Prospective screening of outpatients (primary care, urgent care, ED, telehealth) with acute respiratory illness (ARI).
- October 20, 2023 – May 24, 2024.

Eligibility Criteria

- Age 6 months – 64 years.
- ARI with cough and illness duration ≤7 days.
- No influenza antiviral medication.

Influenza Case Status

- Respiratory specimens were tested using multiplex real-time reverse transcription polymerase chain reaction (RT-PCR) to identify influenza cases; controls were influenza-negative.

ccIIV4 Vaccine Receipt

- Documented receipt ≥14 days prior to illness onset (age ≥9 years) or according to US Advisory Committee on Immunization Practices (ACIP) recommendations (age <9 years).

ccIIV4 Vaccine Effectiveness (VE)

- Estimated as 1 – odds ratio x 100% with adjustment for age and calendar time *a priori,* using logistic regression models.
- Analyses restricted to ccIIV4 recipients and unvaccinated participants.

Conclusions

- ccIIV4 generated substantial real-world effectiveness against medically attended, laboratory-confirmed influenza in 2023-24.
- ccIIV4 effectiveness was highest in children 6 months to 3 years of age and for influenza B in persons 6 months to 64 years.

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Results

Figure 1. Study Flow Chart

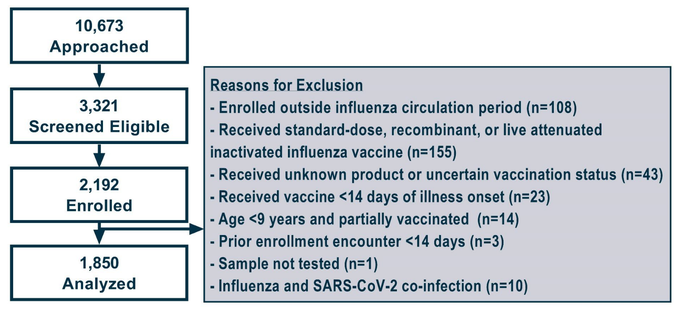


Table. Characteristics of the Study Population

		Total No. of Participants	No. (%) ccIIV4	No. (%) Influenza A Positive	No. (%) Influenza A/H1N1pdm09 Positive	No. (%) Influenza A/H3N2 Positive	No. (%) Influenza B Positive	No. (%) Influenza Negative
Total		1850	470 (25)	356 (19)	267 (14)	56 (3)	149 (8)	1345 (73)
Age	6 months – 3 years	228	75 (33)	33 (14)	27 (12)	6 (3)	4 (2)	191 (85)
	4 – 8 years	230	61 (27)	38 (17)	29 (13)	7 (3)	27 (12)	165 (72)
	9 – 17 years	363	67 (18)	71 (20)	58 (16)	5 (1)	54 (15)	238 (66)
	18 – 64 years	1029	267 (26)	214 (21)	153 (15)	38 (4)	64 (6)	751 (73)
Sex	Female	1079	301 (28)	193 (18)	143 (13)	32 (3)	79 (7)	807 (75)
	Male	771	169 (22)	163 (21)	124 (16)	24 (3)	70 (9)	538 (70)
Race and ethnicity	Non-Hispanic White	1603	421 (26)	308 (19)	233 (15)	46 (3)	134 (8)	1161 (72)
	Hispanic	94	26 (24)	27 (18)	14 (15)	0	8 (8)	66 (70)
	Non-Hispanic Other	147	30 (18)	20 (21)	19 (13)	4 (3)	7 (5)	113 (77)
Self report of high-risk condition*	Yes	817	256 (31)	160 (20)	115 (14)	25 (3)	44 (5)	613 (75)
	No	1033	214 (21)	196 (19)	152 (15)	31 (3)	105 (10)	732 (71)
Self report of COVID-19 vaccination†	Yes	130	121 (93)	22 (17)	13 (10)	8 (6)	2 (2)	106 (82)
	No	1720	349 (20)	334 (19)	254 (15)	48 (3)	147 (9)	1239 (72)

*Based on self-report of asthma or another chronic lung disease, cancer, diabetes, heart disease including high blood pressure, immunocompromising condition, kidney disease, liver disease, obesity, and pregnancy in the 12 months preceding enrollment.
†Receipt of COVID-19 vaccine since September 1, 2023

Figure 2. Influenza Case Status and Week of Symptom Onset

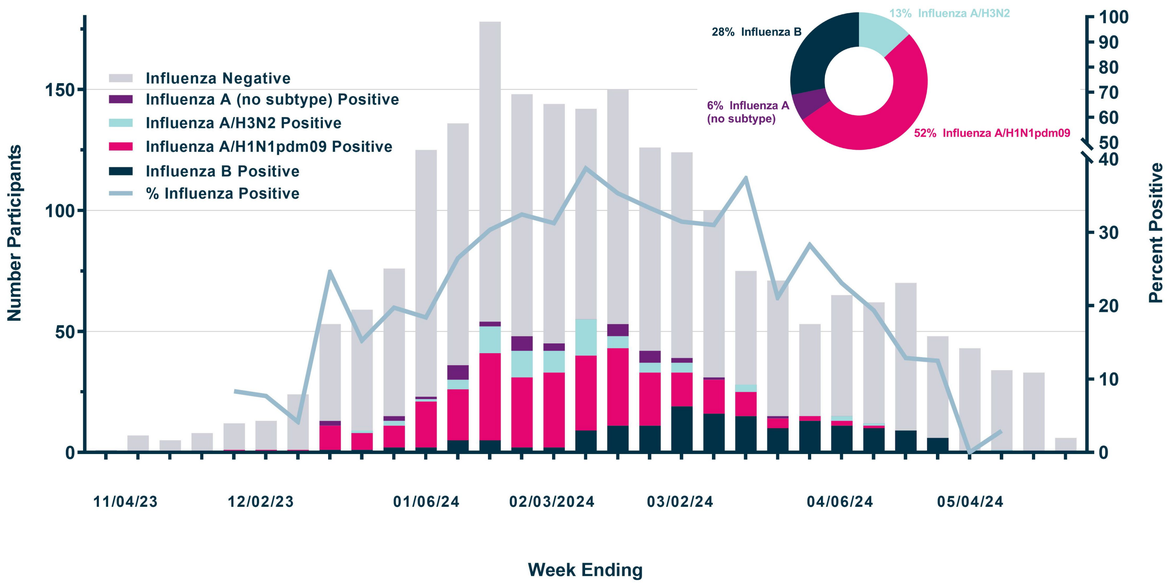
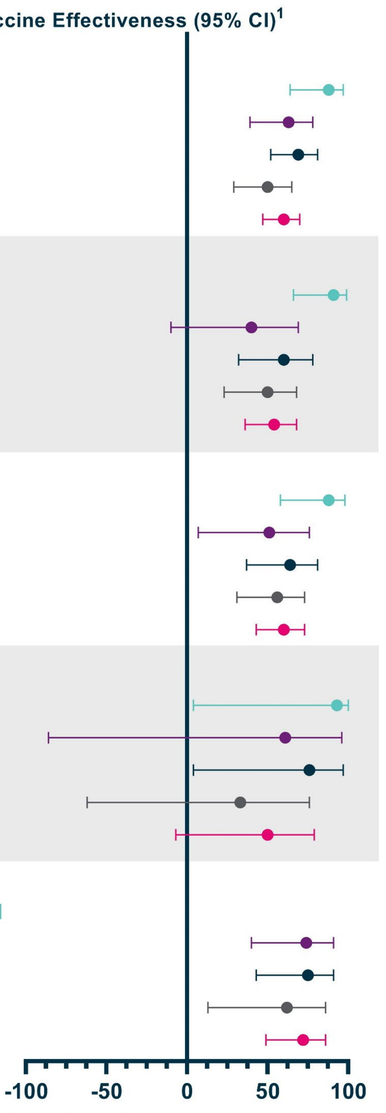


Figure 3. Effectiveness of ccIIV4 by Influenza Type/Subtype and Age Group

	ccIIV4 n/N	Unvaccinated n/N	Adjusted Vaccine Effectiveness (95% CI)[1]
Any Influenza			
6 months - 3 years	3/75	34/153	88 (64, 97)
4 - 17 years	22/128	168/465	63 (39, 78)
6 months - 17 years	25/203	202/618	69 (52, 81)
18 - 64 years	50/267	228/762	50 (29, 65)
6 months - 64 years	75/470	430/1380	60 (47, 70)
A			
6 months - 3 years	3/75	30/149	91 (66, 99)
4 - 17 years	16/122	93/390	40 (-10, 69)
6 months - 17 years	19/197	123/539	60 (32, 78)
18 - 64 years	43/260	171/705	50 (23, 68)
6 months - 64 years	62/457	294/1244	54 (36, 68)
A/H1N1pdm09			
6 months - 3 years	2/74	25/144	88 (58, 98)
4 - 17 years	12/118	75/372	51 (7, 76)
6 months - 17 years	14/192	100/516	64 (37, 81)
18 - 64 years	27/244	126/660	56 (31, 73)
6 months - 64 years	41/436	226/1176	60 (43, 73)
A/H3N2			
6 months - 3 years	1/73	5/124	98 (4, 100)
4 - 17 years	2/108	10/307	61 (-86, 96)
6 months - 17 years	3/181	15/431	76 (4, 97)
18 - 64 years	10/227	28/562	33 (-62, 76)
6 months - 64 years	13/408	43/993	50 (-7, 79)
B			
6 months - 3 years	0/72	4/123	Not estimated
4 - 17 years	6/112	75/372	74 (38, 91)
6 months - 17 years	6/184	79/495	75 (43, 91)
18 - 64 years	7/224	57/591	62 (13, 86)
6 months - 64 years	13/408	136/1086	72 (49, 86)



[1]All models were adjusted for age (spline for all ages and adult models, single year of age for pediatric age groups) and calendar time (pre-peak, peak, post-peak). Influenza A and A/H3N2 models also adjusted for COVID-19 vaccine receipt after September 1, 2023; influenza B models also adjusted for COVID-19 vaccine receipt after September 1, 2023, and presence of ≥1 high-risk medical condition.