

PUBLIC HEALTH GRAND ROUNDS

Strengthening Public Health through Scientific Discourse

Vaccine Effectiveness: Overview of the Methods Toolbox

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.



SCIENCE

Integrity in every study.



DIALOGUE

Every voice matters.



SOCIETY

Working together for better health.

An Introduction

- My experience –
 - MPH research in herpes simplex virus transmission and vaccines
 - Post-MPH work as a clinical trial and observational study coordinator and data analyst
 - PhD research into symptomatic and asymptomatic childhood respiratory viruses and viral coinfections
 - Faculty roles at Wayne State University (2010) and UM Public Health (2014). Research focus in virus epidemiology and vaccines with a special emphasis on work that integrates community and clinical environments.
- COI – My institution receives research funding from CDC, NIH, ARPA-H and philanthropic sources for my team's work. In the past 10 years, my institution has received research funding from Merck for my team's work on RSV epidemiology.

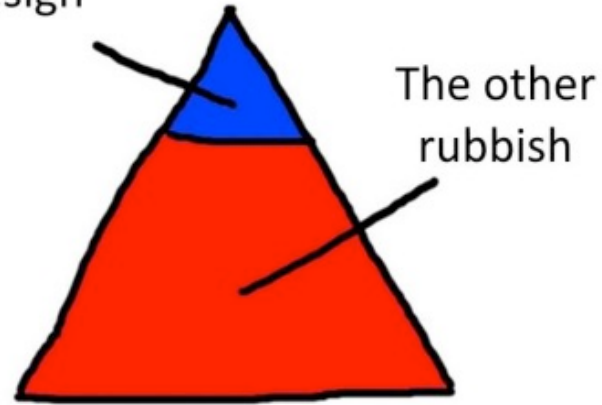


Our Goal is an Accumulation of Evidence



Wagoner, B. et al. (2004),
As reproduced in Blunt et al

Thoughtful, well-conducted studies of
any design



The Rothman-Dahly Evidence Pyramid



**A different
accumulation of tools...**

Blunt, C. The Pyramid Schema: The Origins and Impact of Evidence Pyramids (February 12, 2026). Available at SSRN: <https://ssrn.com/abstract=4297163>

Rothman, K.J. Six Persistent Research Misconceptions. *J GEN INTERN MED* 29, 1060–1064 (2014).

Miguel A. Hernán, Sonia Hernández-Díaz, James M. Robins. Randomized Trials Analyzed as Observational Studies. *Ann Intern Med.* 2013;159:560-562.

“Rothman-Dahly Evidence Pyramid”: <https://zenodo.org/records/18084434/>



Goal: To generate a **body of evidence** that, **taken together**, gives us **timely** information about the vaccine against a **changing** virus landscape.



Across Networks and Populations:

Morbidity and Mortality Weekly Report

Interim Estimates of 2024–2025 Seasonal Influenza Vaccine Effectiveness — Four Vaccine Effectiveness Networks, United States, October 2024–February 2025

Aaron M. Frutos, PhD^{1,2}; Seana Cleary, MPH¹; Emily L. Reeves, MPH¹; Haris M. Ahmad, MPH¹; Ashley M. Price, MPH¹; Wesley H. Self, MD³; Yuwei Zhu, MD³; Basmah Safdar, MD⁴; Ithan D. Peltan, MD⁵; Kevin W. Gibbs, MD⁶; Matthew C. Exline, MD⁷; Adam S. Luring, MD, PhD⁸; Sarah W. Ball, ScD⁹; Malini DeSilva, MD¹⁰; Sara Y. Tartof, PhD¹¹; Kristin Dascomb, MD, PhD¹²; Stephanie A. Irving, MHS¹³; Nicola P. Klein, MD, PhD¹⁴; Brian E. Dixon, PhD^{15,16}; Toan C. Ong, PhD¹⁷; Ivana A. Vaughn, PhD¹⁸; Stacey L. House, MD, PhD¹⁹; Kiran A. Faryar, MD²⁰; Mary Patricia Nowalk, PhD²¹; Manjusha Gaglani, MBBS^{22,23}; Karen J. Wernli, PhD^{24,25}; Vel Murugan, PhD²⁶; Olivia L. Williams, MPH²⁷; Rangaraj Selvarangan, PhD^{28,29}; Geoffrey A. Weinberg, MD³⁰; Mary A. Staat, MD³¹; Natasha B. Halasa, MD³; Leila C. Sahni, PhD³²; Marian G. Michaels, MD³³; Janet A. Englund, MD³⁴; Marie K. Kirby, PhD¹; Diya Surie, MD³⁵; Fatimah S. Dawood, MD³⁵; Benjamin R. Clopper, MPH³⁵; Heidi L. Moline, MD³⁵; Ruth Link-Gelles, PhD³⁵; Amanda B. Payne, PhD³⁵; Elizabeth Harker, MPH¹; Kristina Wielgosz, MPH¹; Zachary A. Weber, PhD⁹; Duck-Hye Yang, PhD⁹; Nathaniel M. Lewis, PhD¹; Jennifer DeCuir, MD, PhD¹; Samantha M. Olson, MPH¹; Jessie R. Chung, MPH¹; Brendan Flannery, PhD¹; Lisa A. Grohskopf, MD¹; Carrie Reed, DSc¹; Shikha Garg, MD¹; Sascha Ellington, PhD¹; CDC Influenza Vaccine Effectiveness Collaborators

Across Subgroups and from Year to Year:

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Influenza Vaccine Effectiveness in the United States during the 2015–2016 Season

Michael L. Jackson, Ph.D., Jessie R. Chung, M.P.H., Lisa A. Jackson, M.D., C. Hallie Phillips, M.Ed., Joyce Benoit, B.S.N., Arnold S. Monto, M.D., Emily T. Martin, Ph.D., Edward A. Belongia, M.D., Huong Q. McLean, Ph.D., Manjusha Gaglani, M.D., Kempapura Murthy, M.P.H., Richard Zimmerman, M.D., Mary P. Nowalk, Ph.D., Alicia M. Fry, M.D., and Brendan Flannery, Ph.D.

N ENGL J MED 377;6 NEJM.ORG AUGUST 10, 2017



Goal: To generate a **body of evidence** that, **taken together**, gives us **timely** information about the vaccine against a **changing** virus landscape.



Synthesis between countries:

Review

Live attenuated influenza vaccine (LAIV): recent effectiveness results from the USA and implications for LAIV programmes elsewhere

Richard Pebody,¹ Jim McMenamin,² Hanna Nohynek³

Pebody R, et al. *Arch Dis Child* 2018;**103**:101–105. doi:10.1136/archdischild-2016-312165

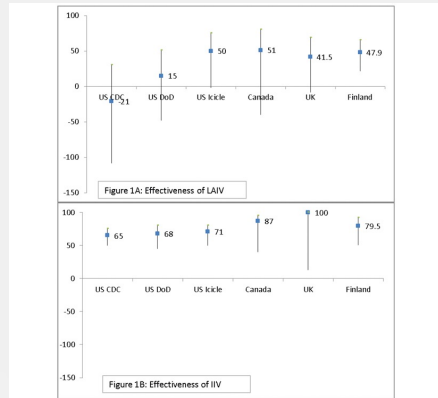


Figure 1 Summary of paediatric vaccine study sites and vaccine effectiveness findings for LAIV and IIV against A(H1N1)pdm09 for 2015/2016 in North America and Europe in children ≤ 17 years of age in 2015/2016 (in Finland, 2 and 3 years old only). All studies used the negative case-control design except the Finland study (population cohort). (A) Effectiveness of LAIV. (B) Effectiveness of IIV. CDC, Centers for Disease Control and Prevention; DoD, Department of Defence; IIV, inactivated influenza vaccine; LAIV, live attenuated influenza vaccine.

Review	
Table 1 Potential studies to investigate reduced LAIV VE hypotheses	
Hypotheses	Study approaches
CDC/DoD A/H1N1pdm09 specific finding — related to chance, methodology, programmatic issues	More highly powered vaccine effectiveness study with larger sample size in eligible population also allowing for stratification by age and/or previous exposure
Replicative fitness of the current A/H1N1pdm09 strain	Comparative shedding study of LAIV vaccinees to compare different vaccine virus formulations
Viral interference/competition between A/H1N1pdm09 vaccine strain and other vaccine viruses in multivalent formulation	In vitro and vivo challenge studies to compare viral shedding patterns
Prior vaccination with LAIV or IIV resulting in specific immunological interference with H1N1pdm09 vaccine virus replication	VE and shedding studies to compare groups with different prior vaccine exposure
Repeat LAIV vaccination resulting in broader, longer term immunological changes affecting all viruses (mimicking adult response)	Serological and cell-mediated LAIV immunity studies
CDC, Centers for Disease Control and Prevention; DoD, Department of Defence; IIV, inactivated influenza vaccine; LAIV, live attenuated influenza vaccine; VE, vaccine effectiveness.	

“... a series of studies are required to determine the effectiveness of LAIV against a range of laboratory and clinical end-points and to measure VE and to explore further which explanatory factors (table 1) are most likely to explain the earlier reduction in A(H1N1)pdm09 effectiveness.”



When Methodological Tools are Compared

RESEARCH ARTICLES

The test-negative design: validity, accuracy and precision of vaccine efficacy estimates compared to the gold standard of randomised placebo-controlled clinical trials

G De Serres (gaston.deserres@inspq.qc.ca)¹, D M Skowronski², X W Wu³, C S Ambrose³

1. Institut national de santé publique du Québec and Department of Social and Preventive Medicine, Laval University, Quebec, Canada
2. British Columbia Center for Disease Control, Vancouver Canada
3. MedImmune, Gaithersburg, MD, USA

Citation style for this article:
De Serres G, Skowronski DM, Wu XW, Ambrose CS. The test-negative design: validity, accuracy and precision of vaccine efficacy estimates compared to the gold standard of randomised placebo-controlled clinical trials. Euro Surveill. 2013;18(37):pii=20585. Available online: <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20585>

Article submitted on 09 April 2013 / published on 12 September 2013

2013: “In this analysis, we confirm that estimates of efficacy and their 95% CIs were similar when derived according to the classical per-protocol RCT analysis or various TND approaches and this was observed in children and the elderly at respectively high or reduced efficacy values.”

JAMA Network **Open**

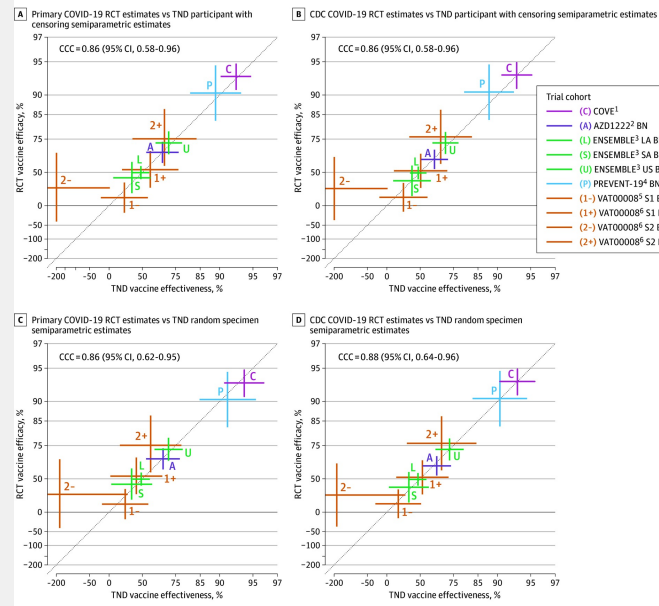
Original Investigation | Statistics and Research Methods

Evaluating the Test-Negative Design for COVID-19 Vaccine Effectiveness Using Randomized Trial Data

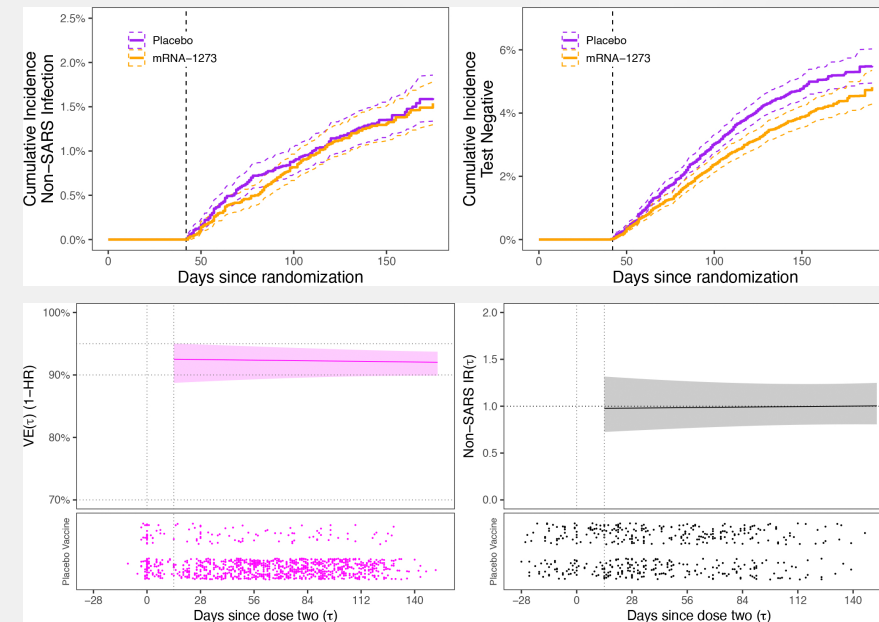
A Secondary Cross-Protocol Analysis of 5 Randomized Clinical Trials

Leah I. B. Andrews, MS, M. Elizabeth Halloran, MD, DSc; Kathleen M. Neuzil, MD; Lars van der Laan, MA; Yunda Huang, PhD; Jessica Andriessen, PhD; Mayur Patel, MPH; Leigh H. Fisher, PhD; Holly Janes, PhD; Nadine Rouphael, MD; Stephen R. Walsh, MD; Deborah A. Theodore, MD; Hong-Van Tieu, MD; Magdalena Sobieszczyk, MD; Hana M. El Sahly, MD; Lindsey R. Baden, MD; Ann R. Falsey, MD; Thomas B. Campbell, MD; Colleen F. Kelley, MD, MPH; Catherine Mary Healy, MD; Lilly Immergluck, MD; Benjamin Luft, MD; Ian Hirsch, PhD; Guy de Booy, MBECh, MPH; Carla Troyers, PhD; Frances Braddy, MPH, MD; Kelsey M. Sumner, PhD; Brendan Flannery, PhD; Dean Follmann, PhD; Peter B. Gilbert, PhD, for the COVID-19 Prevention Network (COVNP)

JAMA Network Open. 2025;8(5):e2512763. doi:10.1001/jamanetworkopen.2025.12763



Validating and leveraging non-SARS-CoV-2 respiratory infection as a negative control outcome in a phase 3 COVID-19 vaccine trial with extended observational follow-up. Am J Epidemiol. 2026 Jan 8;195(1):168-177.



Randomized Controlled Trials

Placebo-controlled

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Comparative Efficacy of Inactivated and Live Attenuated Influenza Vaccines

Arnold S. Monto, M.D., Suzanne E. Ohmit, Dr.P.H., Joshua G. Petrie, M.P.H.,
Emileigh Johnson, B.S., Rachel Truscon, M.P.H., Esther Teich, M.A.,
Judy Rotthoff, R.N., Matthew Boulton, M.D., M.P.H.,
and John C. Victor, Ph.D., M.P.H.

N ENGL J MED 361:13 NEJM.ORG SEPTEMBER 24, 2009

Eligible subjects were healthy men and women 18 to 49 years of age. Persons with any health condition for which the inactivated vaccine was specifically recommended and persons for whom either vaccine was contraindicated were excluded.

Table 1. Baseline Characteristics of the 1952 Subjects, According to Study Group, during the 2007–2008 Influenza Season in Michigan.*

Characteristic	TIV Group (N=814)	LAIV Group (N=813)	Placebo Group (N=325) [†]	Total (N=1952)
Total participants — %	41.7	41.6	16.7	100.0
Age — yr	23.2±7.4	23.5±7.7	22.9±6.7	23.3±7.4

	Confirmation of Symptomatic Influenza [‡]			Cumulative Incidence of Influenza		
	TIV (N=813)	LAIV (N=814)	Placebo (N=325)	TIV (N=813)	LAIV (N=814)	Placebo (N=325)
	<i>no. of participants (%)</i>					
Positive culture	21 (2.6)	38 (4.7)	31 (9.5)			
Positive PCR	28 (3.4)	56 (6.9)	35 (10.8)			
Positive culture, positive PCR, or both	28 (3.4)	56 (6.9)	35 (10.8)			

Contemporary Randomized Controlled Trials



Product-specific differences in specific populations.

Immunogenicity of High-Dose Egg-Based, Recombinant, and Cell Culture-Based Influenza Vaccines Compared With Standard-Dose Egg-Based Influenza Vaccine Among Health Care Personnel Aged 18-65 Years in 2019-2020. Naleway AL, Kim SS, Flannery B, Levine MZ, Murthy K, Sambhara S, Gangappa S, Edwards LJ, Ball S, Grant L, Zunie T, Cao W, Gross FL, Groom H, Fry AM, Hunt D, Jeddy Z, Mishina M, Wesley MG, Spencer S, Thompson MG, Gaglani M, Dawood FS. *Open Forum Infect Dis.* 2023 Apr 21;10(6):ofad223.

A randomized controlled trial of antibody response to 2018-19 cell-based vs. egg-based quadrivalent inactivated influenza vaccine in children. Moehling KK, Zimmerman RK, Nowalk MP, Jeng Lin C, Martin JM, Alcorn JF, Susick M, Burroughs A, Holiday C, Flannery B, Levine MZ. *Vaccine.* 2020 Jul 14;38(33):5171-5177. doi: 10.1016/j.vaccine.2020.06.023. Epub 2020 Jun 21. PMID: 32580919; PMCID: PMC7367053.

Clinical trial to assess immunogenicity of high-dose, adjuvanted, and recombinant influenza vaccines against cell-grown A(H3N2) viruses in adults 65 to 74 years, 2017-2018. Belongia EA, Levine MZ, Olaiya O, Gross FL, King JP, Flannery B, McLean HQ. *Vaccine.* 2020 Mar 30;38(15):3121-3128. doi: 10.1016/j.vaccine.2020.02.055. Epub 2020 Mar 4. PMID: 32145994.

Comparison of the immunogenicity of adjuvanted and conventional egg-based quadrivalent influenza vaccines among healthcare personnel in Lima, Peru: A randomized controlled trial. Marcenac P, Soto G, Yau T, Carreon JD, Romero C, Gonzales M, La Rosa S, Arriola CS, Prouty M, Díaz RAH, Romero FA, Llanos-Cuentas A, Prado EDM, Silva M, Fowlkes A, Levine MZ, Azziz-Baumgartner E, Duca LM, Neyra J. *Int J Infect Dis.* 2026 Jan;162:108205. doi: 10.1016/j.ijid.2025.108205. Epub 2025 Nov 11. PMID: 41232749; PMCID: PMC13244592.

Detailed serologic assessments of vaccine effect, including repeat vaccination.

Redirecting antibody responses from egg-adapted epitopes following repeat vaccination with recombinant or cell culture-based versus egg-based influenza vaccines. Liu F, Gross FL, Joshi S, Gaglani M, Naleway AL, Murthy K, Groom HC, Wesley MG, Edwards LJ, Grant L, Kim SS, Sambhara S, Gangappa S, Tumpey T, Thompson MG, Fry AM, Flannery B, Dawood FS, Levine MZ. *Nat Commun.* 2024 Jan 4;15(1):254. doi: 10.1038/s41467-023-44551-x. PMID: 38177116; PMCID: PMC10767121.

Improved Immune Response Against Influenza A Viruses With Receipt of a Recombinant Influenza Vaccine in Healthcare Personnel With Prior Low Antibody Response to Egg-Based Influenza Vaccines, Israel, 2019-2020. Sumner KM, Katz M, Hirsch A, Peretz A, Greenberg D, Martin ET, Truscon R, Edwards LJ, Grant L, Noble EK, Newes-Adeyi G, Dreiherr J, Fry A, Flannery B, Azziz-Baumgartner E, Monto AS, Levine MZ, Thompson M, Balicer R, Fowlkes A. *J Infect Dis.* 2026 Apr 29;233(4):e1011-e1021. doi: 10.1093/infdis/jiaf605. PMID: 41330417.

Effect of Repeat Vaccination on Immunogenicity of Quadrivalent Cell-Culture and Recombinant Influenza Vaccines Among Healthcare Personnel Aged 18-64 Years: A Randomized, Open-Label Trial. Gaglani M, Kim SS, Naleway AL, Levine MZ, Edwards L, Murthy K, Dunnigan K, Zunie T, Groom H, Ball S, Jeddy Z, Hunt D, Wesley MG, Sambhara S, Gangappa S, Grant L, Cao W, Gross FL, Mishina M, Fry AM, Thompson MG, Dawood FS, Flannery B. *Clin Infect Dis.* 2023 Feb 8;76(3):e1168-e1176. doi: 10.1093/cid/ciac683. PMID: 36031405; PMCID: PMC9907492.



Observational Tools



Cohorts



Case-
Control



Test-
Negative



Observational Tools



Cohorts



Case-
Control



Test-
Negative



Vaccine effectiveness against mild to moderate illness.

Influenza Vaccine Effectiveness in a Low-Income, Urban Community Cohort. Smithgall M, Vargas CY, Reed C, Finelli L, LaRussa P, Larson EL, Saiman L, Stockwell MS. Clin Infect Dis. 2016 Feb 1;62(3):358-360.

Substantial Influenza Vaccine Effectiveness in Households With Children During the 2013-2014 Influenza Season, When 2009 Pandemic Influenza A(H1N1) Virus Predominated. Ohmit SE, Petrie JG, Malosh RE, Johnson E, Truscon R, Aaron B, Martens C, Cheng C, Fry AM, Monto AS. J Infect Dis. 2016 Apr 15;213(8):1229-36.

Estimated Effectiveness of Influenza Vaccines in Preventing Secondary Infections in Households. Grijalva CG, Nguyen HQ, Zhu Y, Mellis AM, McGonigle T, Meece JK, Biddle JE, Halasa NB, Reed C, Fry AM, Yang Y, Belongia EA, Talbot HK, Rolfes MA. JAMA Netw Open. 2024 Nov 4;7(11):e2446814.

Effectiveness of Influenza Vaccines in the HIVE Household Cohort Over 8 Years: Is There Evidence of Indirect Protection? Malosh RE, Petrie JG, Callear A, Truscon R, Johnson E, Evans R, Bazzi L, Cheng C, Thompson MS, Martin ET, Monto AS. Clin Infect Dis. 2021 Oct 5;73(7):1248-1256.

Vaccine effectiveness against all infection.

Effectiveness of Bivalent mRNA COVID-19 Vaccines in Preventing SARS-CoV-2 Infection in Children and Adolescents Aged 5 to 17 Years. Feldstein LR, Britton A, Grant L, Wiegand R, Ruffin J, Babu TM, Briggs Hagen M, Burgess JL, Caban-Martinez AJ, Chu HY, Ellingson KD, Englund JA, Hegmann KT, Jeddy Z, Lauring AS, Lutrick K, Martin ET, Mathenge C, Meece J, Midgley CM, Monto AS, Newes-Adeyi G, Odame-Bamfo L, Olsho LEW, Phillips AL, Rai RP, Saydah S, Smith N, Steinhardt L, Tyner H, Vandermeer M, Vaughan M, Yoon SK, Gaglani M, Naleway AL. JAMA. 2024 Feb 6;331(5):408-416. **Respiratory syncytial virus (RSV) vaccine effectiveness and antibody correlates of protection among older adults in the Community Vaccine Effectiveness (CoVE) observational study.** Godonou ET, Callear AP, Juntilla-Raymond CL, Raji D, Smith M, Rumpfelt KE, Midgley CM, Feldstein LR, Jones JM, Hagen MB, Eisenberg MC, Lauring AS, Monto AS, Wagner AL, Martin ET. EBioMedicine. 2025 Nov;121:105961.



Observational Tools



Cohorts



Case-
Control



Test-
Negative

Lesson Learned: Healthy vaccinee bias is an issue when risk period and outcome definitions are imprecise and when health status is not accounted for.

Evidence of bias in estimates of influenza vaccine effectiveness in seniors. Jackson LA, Jackson ML, Nelson JC, Neuzil KM, Weiss NS. *Int J Epidemiol.* 2006 Apr;35(2):337-44.

Influenza vaccine for community-acquired pneumonia. Belongia EA, Shay DK. *Lancet.* 2008 Aug 2;372(9636):352-4.

Cohort studies with prospective enrollment require defined exposure, defined outcome, and defined target population prior to study execution. However, ascertainment of a pre-specified intended defined outcome in a defined target population is operationally challenging. (The “Babe Ruth problem”).

Example: *Households with school-aged children*

From 2010 to 2022

11,714 illnesses (7,269 in children)

789 Influenza A detections

298 Influenza B detections

<20% lead to medical visits

~200 medical visits, <5 hospitalizations

J Infect Dis. 2025 Jul 16;232(Suppl 1):S101–S108.

In-season severity assessment

CDC assesses the severity of weekly influenza activity using information on influenza-like illness, flu-related hospitalizations, and flu-coded deaths. To classify the severity of the season, CDC uses the highest weekly values observed from October 1, 2025, through the most recent week of available data, for the three indicators. Based on that data, the 2025-2026 season's severity is currently classified as:

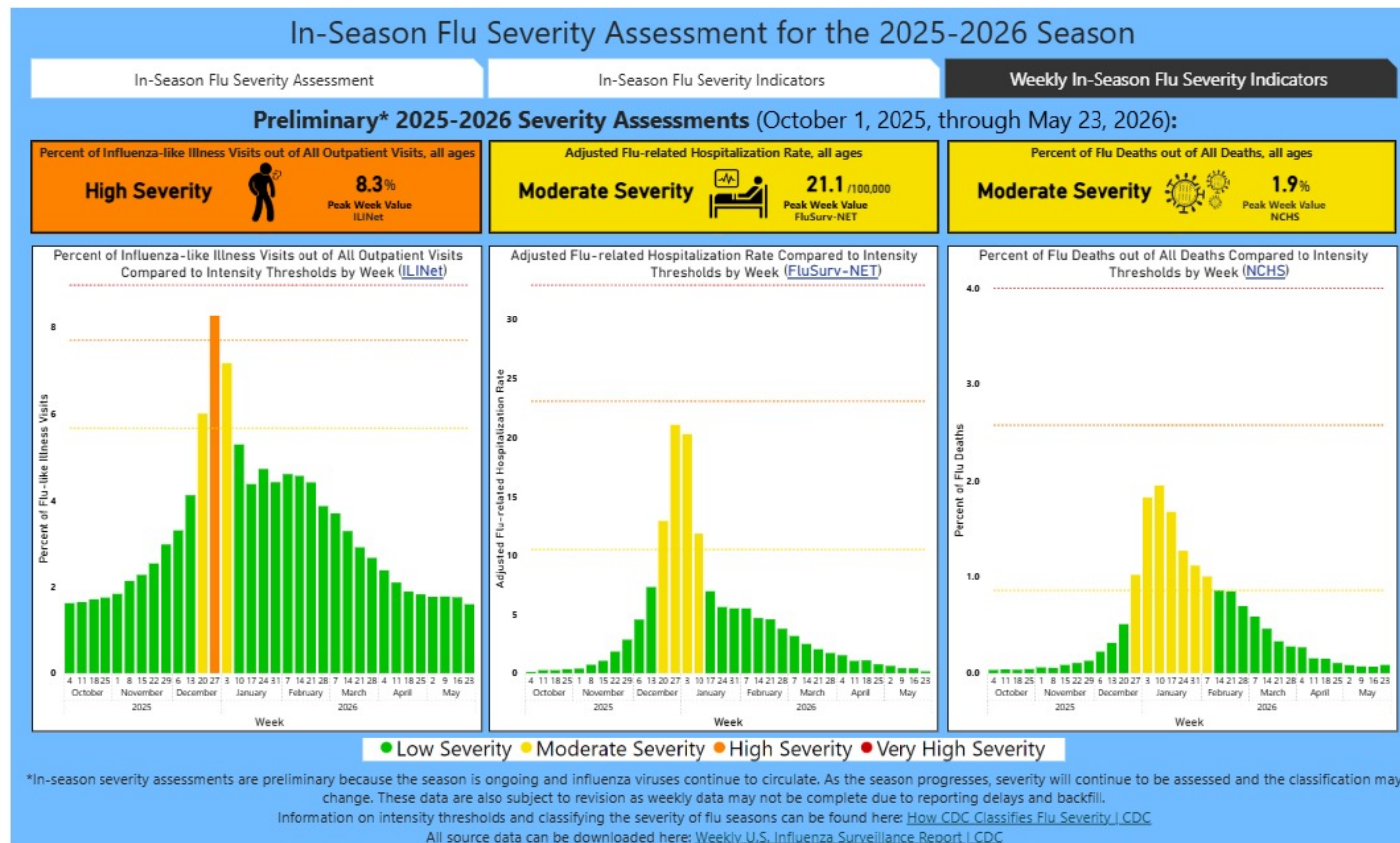
ON THIS PAGE

[In-season severity assessment](#)

[How CDC determines weekly flu severity](#)

[Data sources](#)

[Limitations](#)




<https://www.cdc.gov/flu-burden/php/surveillance/in-season-severity.html>
Accessed June 9, 2026



Observational Tools

 Cohorts

 Case-
Control


 Test-
Negative


Case-Driven Designs



Observational Tools

 Cohorts

 Case-Control

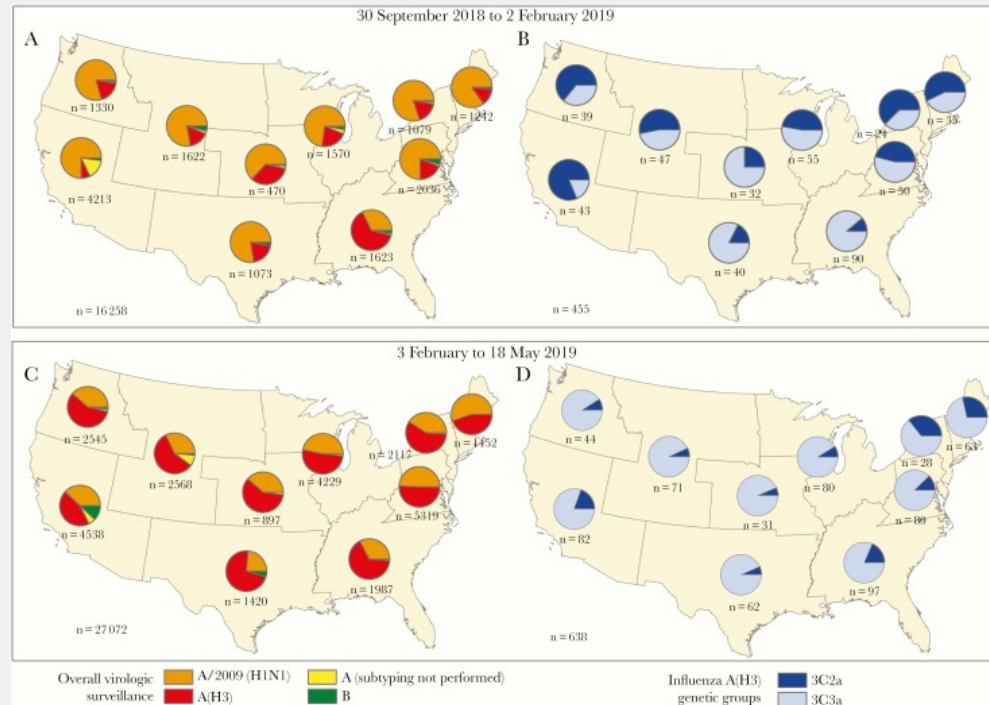
 Test-Negative

Case-Driven Designs

<i>12-year cohort of households with school-aged children</i>	<i>1 season of US Influenza VE Network (2023-2024)</i>	<i>1 season of IVY (hospital-based) network</i>
<p>Cases: 789 Influenza A cases 298 Influenza B cases</p> <p>MAARI (Medically-Attended Acute Respiratory Illness): ~200 medical visits for influenza</p> <p>Hospitalizations: <5 hospitalizations for influenza</p>	<p>MAARI (Medically-Attended Acute Respiratory Illness): 1,780 with influenza 6,629 total</p>	<p>Hospitalizations: 714 hospitalizations for influenza</p>

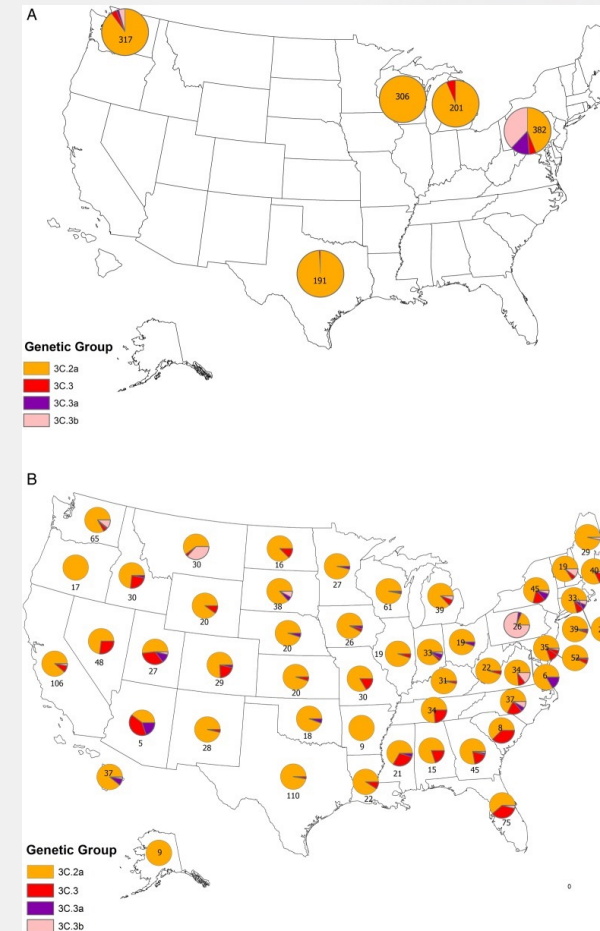
Case-Driven Designs

2017-2018: Midseason change in subtype and H3 strain



J Infect Dis. 2019 Oct 30;221(1):8–15. doi: 10.1093/infdis/jiz543

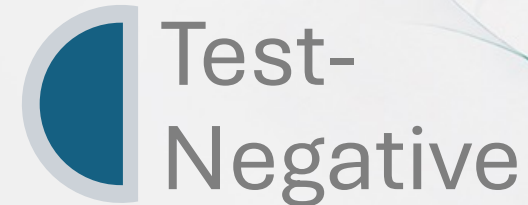
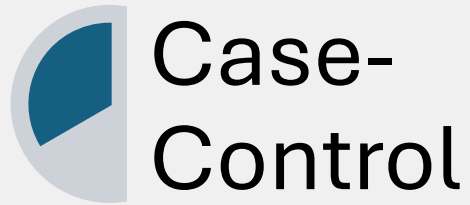
2014-2015: Geographic variation in influenza strains (and in VE)



J Infect Dis. 2016 May 6;214(7):1010–1019. doi: 10.1093/infdis/jiw181



Observational Tools

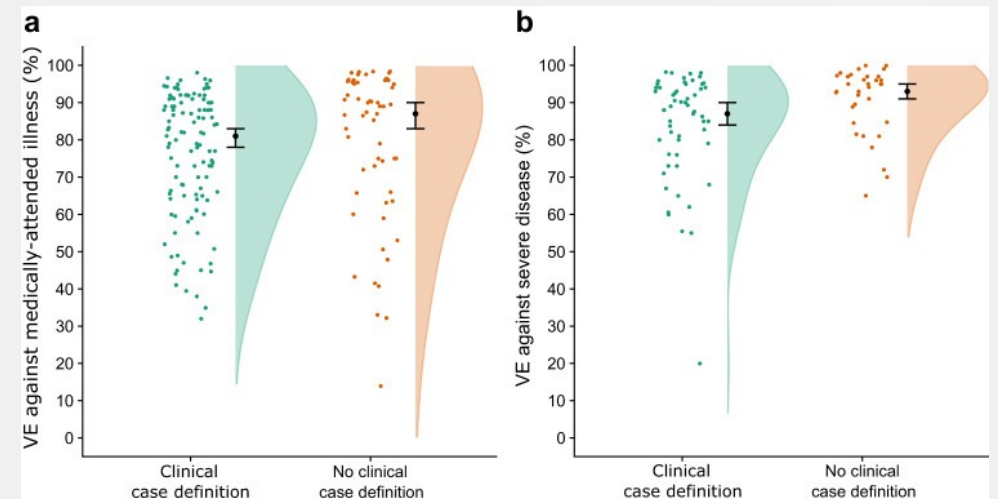


Lesson Learned: The use of community-based controls leads to selection bias when estimating the reduction of medically-attended ARI.

Including controls who are not seeking healthcare will lead to a more favorable VE estimate.

[Theoretical framework for retrospective studies of the effectiveness of SARS-CoV-2 vaccines.](#) Lewnard JA, et al. *Epidemiology*. 2021;32:508–517

Lesson Learned: The lack of a clinically-based case definition will lead to an over-estimation of VE. Estimates from a 2023 systematic review:



The need for a clinical case definition in test-negative design studies estimating vaccine effectiveness. Sullivan, S.G., Khvorov, A., Huang, X. *et al. npj Vaccines* 8, 118 (2023).

Observational Tools



Cohorts



Case-
Control



Test-
Negative

- Resource efficient
- Adaptable to rapidly changing viruses
- Timely
- *But* require careful attention to internal validity
 - Clinical case definition with attention to severity of disease
 - Appropriately restricted to clinical group of interest
 - Health status (i.e. frailty) is measured and accounted for



Continued innovation and validation using CDC TND platforms

Selection of controls.

Influenza Vaccine Effectiveness in the Inpatient Setting: Evaluation of Potential Bias in the Test-Negative Design by Use of Alternate Control Groups. Segaloff HE, Cheng B, Miller AV, Petrie JG, Malosh RE, Cheng C, Lauring AS, Lamerato LE, Ferdinands JM, Monto AS, Martin ET. Am J Epidemiol. 2020 Mar 2;189(3):250-260.

Assessment and mitigation of bias in influenza and COVID-19 vaccine effectiveness analyses - IVY Network, September 1, 2022-March 30, 2023. Lewis NM, Harker EJ, Leis A, Zhu Y, Talbot HK, Grijalva CG, Halasa N, Chappell JD, Johnson CA, Rice TW, Casey JD, Lauring AS, Gaglani M, Ghamande S, Columbus C, Steingrub JS, Shapiro NI, Duggal A, Felzer J, Prekker ME, Peltan ID, Brown SM, Hager DN, Gong MN, Mohamed A, Exline MC, Khan A, Wilson JG, Mosier J, Qadir N, Chang SY, Ginde AA, Mohr NM, Mallow C, Harris ES, Johnson NJ, Srinivasan V, Gibbs KW, Kwon JH, Vaughn IA, Ramesh M, Safdar B, DeCuir J, Surie D, Dawood FS, Ellington S, Self WH, Martin ET. Vaccine. 2025 Jan 1;43(Pt 2):126492.

Durability of immunity and impact of population immunity.

Evaluation of correlates of protection against influenza A(H3N2) and A(H1N1)pdm09 infection: Applications to the hospitalized patient population. Petrie JG, Martin ET, Truscon R, Johnson E, Cheng CK, McSpadden EJ, Malosh RE, Lauring AS, Lamerato LE, Eichelberger MC, Ferdinands JM, Monto AS. Vaccine. 2019 Feb 28;37(10):1284-1292.

Waning Vaccine Effectiveness Against Influenza-Associated Hospitalizations Among Adults, 2015-2016 to 2018-2019, United States Hospitalized Adult Influenza Vaccine Effectiveness Network. Ferdinands JM, Gaglani M, Martin ET, Monto AS, Middleton D, Silveira F, Talbot HK, Zimmerman R, Patel M. Clin Infect Dis. 2021 Aug 16;73(4):726-729.

Reduced Effectiveness of Repeat Influenza Vaccination: Distinguishing Among Within-Season Waning, Recent Clinical Infection, and Subclinical Infection. Bi Q, Dickerman BA, Nguyen HQ, Martin ET, Gaglani M, Wernli KJ, Balasubramani GK, Flannery B, Lipsitch M, Cobey S; US Flu Vaccine Effectiveness Network Investigators. J Infect Dis. 2024 Dec 16;230(6):1309-1318.

Clinical severity of, and effectiveness of mRNA vaccines against, covid-19 from omicron, delta, and alpha SARS-CoV-2 variants in the United States: prospective observational study. Lauring AS, Tenforde MW, Chappell JD, Gaglani M, Ginde AA, McNeal T, Ghamande S, Douin DJ, Talbot HK, Casey JD, Mohr NM, Zepeski A, Shapiro NI, Gibbs KW, Files DC, Hager DN, Shehu A, Prekker ME, Erickson HL, Exline MC, Gong MN, Mohamed A, Johnson NJ, Srinivasan V, Steingrub JS, Peltan ID, Brown SM, Martin ET, Monto AS, Khan A, Hough CL, Busse LW, Ten Lohuis CC, Duggal A, Wilson JG, Gordon AJ, Qadir N, Chang SY, Mallow C, Rivas C, Babcock HM, Kwon JH, Halasa N, Grijalva CG, Rice TW, Stubblefield WB, Baughman A, Womack KN, Rhoads JP, Lindsell CJ, Hart KW, Zhu Y, Adams K, Schrag SJ, Olson SM, Kobayashi M, Verani JR, Patel MM, Self WH; Influenza and Other Viruses in the Acutely Ill (IVY) Network. BMJ. 2022 Mar 9;376:e069761.

Accounting for health status, chronic disease, and clinical decision making.

Comparison of a frailty short interview to a validated frailty index in adults hospitalized for acute respiratory illness. Petrie JG, Martin ET, Zhu Y, Wyatt DG, Kaniclides A, Ferdinands JM, Monto AS, Trabue C, Talbot HK. Vaccine. 2019 Jun 27;37(29):3849-3855.

Does Home COVID-19 Testing Bias COVID-19 Vaccine Effectiveness Estimates? Nowalk MP, Balasubramani GK, D'Agostino H, Zimmerman RK, Monto AS, Martin ET, Nguyen HQ, Gaglani M, Mamawala M, Tartof S, Lewin BJ, Wernli K, Wickersham B, Talbot HK, Grijalva CG, Chung JR, Flannery B; U.S. Flu VE Network Investigators. Am J Prev Med. 2026 Jan;70(1):108096.

Influenza Vaccine Effectiveness and Statin Use Among Adults in the United States, 2011-2017. Havers FP, Chung JR, Belongia EA, McLean HQ, Gaglani M, Murthy K, Zimmerman RK, Nowalk MP, Jackson ML, Jackson LA, Monto AS, Petrie JG, Fry AM, Flannery B. Clin Infect Dis. 2019 May 2;68(10):1616-1622.

Exposure and outcome classification.

Vaccine-associated attenuation of subjective severity among outpatients with influenza. Chung JR, Kim SS, Flannery B, Smith ME, Dunnigan K, Raiyani C, Murthy K, Gaglani M, Jackson ML, Jackson LA, Bear T, Moehling Geffel K, Nowalk MP, Zimmerman RK, Martin ET, Lamerato L, McLean HQ, King JP, Belongia EA, Thompson MG, Patel M. Vaccine. 2022 Jul 30;40(32):4322-4327.

K-medoids clustering of hospital admission characteristics to classify severity of influenza virus infection. Leis AM, McSpadden E, Segaloff HE, Lauring AS, Cheng C, Petrie JG, Lamerato LE, Patel M, Flannery B, Ferdinands J, Karvonen-Gutierrez CA, Monto A, Martin ET. Influenza Other Respir Viruses. 2023 Mar 7;17(3):e13120.

Ascertainment of vaccination status by self-report versus source documentation: Impact on measuring COVID-19 vaccine effectiveness. Stephenson M, Olson SM, Self WH, Ginde AA, Mohr NM, Gaglani M, Shapiro NI, Gibbs KW, Hager DN, Prekker ME, Gong MN, Steingrub JS, Peltan ID, Martin ET, Reddy R, Busse LW, Duggal A, Wilson JG, Qadir N, Mallow C, Kwon JH, Exline MC, Chappell JD, Lauring AS, Baughman A, Lindsell CJ, Hart KW, Lewis NM, Patel MM, Tenforde MW; IVY Network Investigators. Influenza Other Respir Viruses. 2022 Nov;16(6):1101-1111.

Impact of accounting for correlation between COVID-19 and influenza vaccination in a COVID-19 vaccine effectiveness evaluation using a test-negative design. Payne AB, Ciesla AA, Rowley EAK, Weber ZA, Reese SE, Ong TC, Vazquez-Benitez G, Naleway AL, Klein NP, Embi PJ, Grannis SJ, Kharbanda AB, Gaglani M, Tenforde MW, Link-Gelles R; VISION Network. Vaccine. 2023 Dec 12;41(51):7581-7586.