Assessing High-Dose Versus Standard Dose Influenza Vaccine Protection Against Cardiovascular and Respiratory Hospitalizations

The study and publication of this infographic were funded by **Sanofi**.

Microbiol Infect Dis AMJ. 2025; https://doi.org/10.33590/microbiolinfectdisam/OVZF8370

STUDY OVERVIEW

Cardiovascular Burden of Influenza

Influenza infection is associated with increased risk of acute cardiovascular events[1]

Older adults are particularly vulnerable to the cardiovascular effects of influenza infection[1,2]

AHA/ACC guidelines recommend annual influenza vaccination for patients with established cardiovascular disease[3,4]

HD-IIV

Contains four-times the antigen of SD-IIV[5]

Was developed to provide increased protection in older adults[5]

Has demonstrated superior efficacy against LCI in a pivotal RCT[6]

FLUNITY-HD Study Design

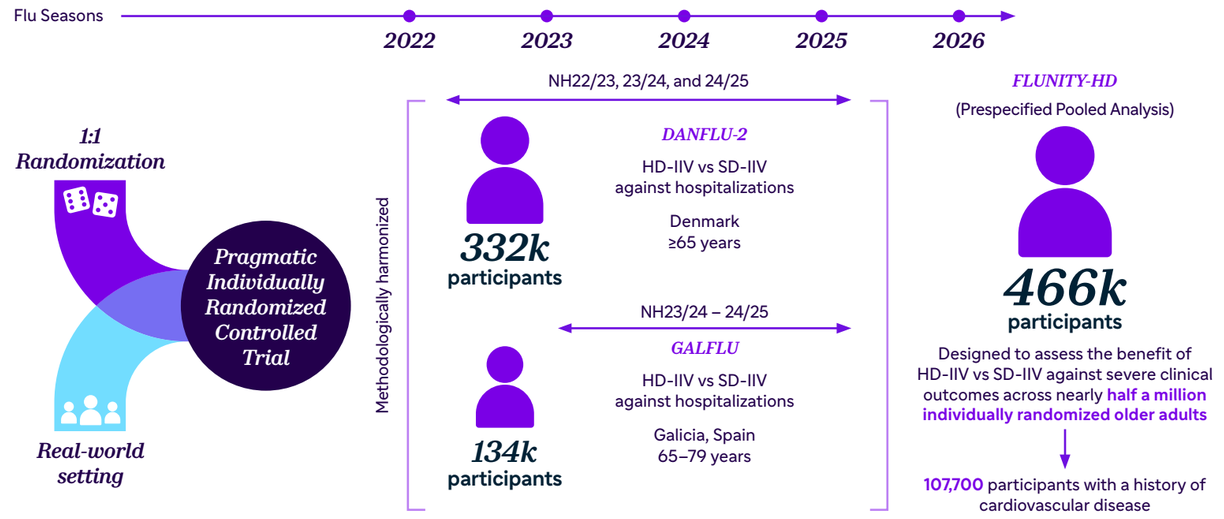
Pre-specified pooled analysis of methodologically harmonized, individually randomized **DANFLU-2 and GALFLU trials**[6-8]

The **SD-IIV** used are the **standard of care** in the populations and geography under study and are **licensed by the EMA**[6-8]

Pragmatic design using real-world healthcare registry data for all baseline data collection and follow-up[7]

Conducted across **three influenza seasons** (2022/23–2024/25) with follow-up **14 days** post-vaccination through May 31st of the following year[9,10]

Largest ever individually randomized influenza vaccine effectiveness study[6-8]

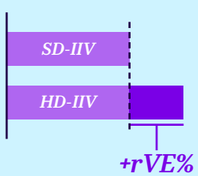


aVE:

Outcomes in a vaccinated cohort compared to those in an unvaccinated or placebo cohort[11]

rVE:

Additional benefit of high-dose vaccine compared to standard-dose vaccine, not absolute protection rates[11]



rVE in FLUNITY-HD shows how much **additional protection** older adults gain by choosing HD-IIV over SD-IIV[7]

ENDPOINTS FROM SECONDARY ANALYSES

Cardiovascular Hospitalizations[9]

Additional benefit of HD-IIV compared to SD-IIV

Consistent benefit regardless of baseline cardiovascular disease status

Heart Failure[9]

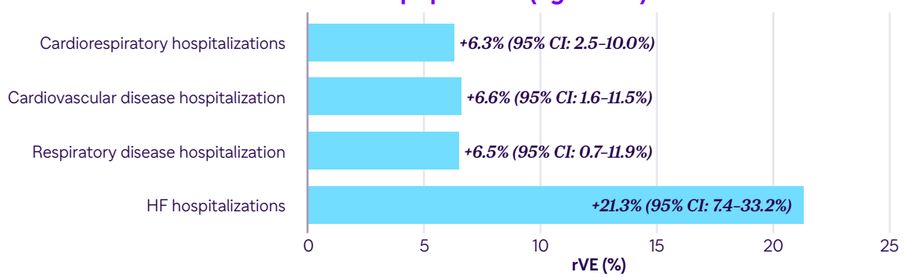
Consistent benefit regardless of baseline HF status, including both incident and recurrent HF hospitalizations

+21.3% rVE for HF hospitalizations

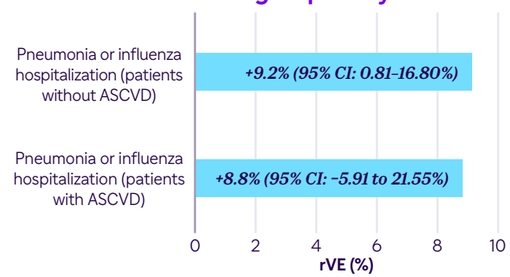
ASCVD Subgroup Analysis[10]

Consistent protection in patients with and without ASCVD

Overall population (aged 65+)



ASCVD Subgroup Analysis



SUMMARY OF RESULTS

HD-IIV demonstrated *superior protection* compared to SD-IIV against cardio-respiratory hospitalizations. This reduction was driven by both cardiovascular and respiratory hospitalizations.[9]

21%

HF hospitalization risk reduced by approximately *21%* with HD-IIV versus SD-IIV[9]

Benefits of HD-IIV over SD-IIV remained consistent across *patients with and without ASCVD*, with a trend in favor of HD-IIV in higher-risk groups.[10]

Abbreviations:

ACC: American College of Cardiology; AHA: American Heart Association; ASCVD: atherosclerotic cardiovascular disease; aVE: absolute vaccine effectiveness; HD-IIV: high-dose inactivated influenza vaccine; HF: heart failure; LCI: laboratory-confirmed influenza; rVE: relative vaccine effectiveness; SD-IIV: standard-dose inactivated influenza vaccine; vs: versus.

References:

1. Chow EJ et al. Ann Intern Med. 2020;173(8):605-13.
2. Nguyen JL et al. JAMA Cardiol. 2016;1(3):274-81.
3. Smith SC et al. Circulation. 2006;113(19):2363-72.
4. Virani SS et al. Circulation. 2023;148(9):e9-119.
5. DiazGranados CA et al. N Engl J Med. 2014;371(7):635-45.
6. Johansen ND et al. JAMA Cardiol. 2025;DOI:10.1001/jamacardio.2025.3460.
7. Johansen ND et al. Lancet . 2025;DOI: 10.1016/S0140-6736(25)01742-8.
8. Tor Biering-Sørensen. NCT06506812. https://clinicaltrials.gov/study/NCT06506812.
9. Johansen ND et al. Circulation. 2025;DOI: 10.1161/CIRCULATIONAHA.125.077801.
10. Pareek M et al. Abstract presented at AHA Scientific Sessions, November 7-10, 2025.
11. Lewis NM et al. Clin Infect Dis. 2022;75(1):170-5.

LEARN MORE

POOLED ANALYSIS OF HOSPITALIZATION OUTCOMES IN OLDER ADULTS

MAT-US-2506845 V1.0 P EXP DATE 10/11/2026