



Fluzone® (Influenza Vaccine) Portfolio and Influenza Immunization Update

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Our Credo

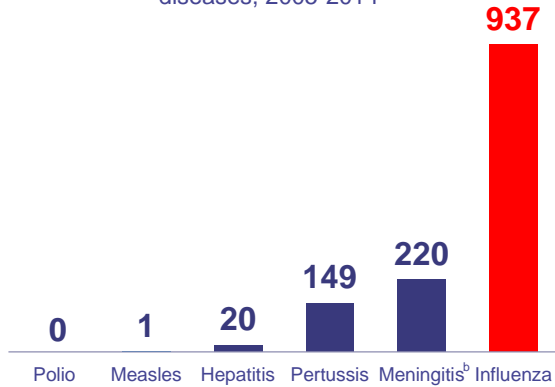


Sanofi Pasteur believes in a world in which no one suffers or dies from a vaccine-preventable disease.

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Influenza is a Leading Cause of Vaccine-Preventable Deaths in Children in the US

US pediatric^a deaths from vaccine-preventable diseases, 2005-2014¹



^a ≤14 years of age

^b Meningococcal meningitis

^c Based on pediatric patients who died from the flu, whose vaccination status was known and who were eligible to receive a flu vaccine.

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References

1. National Vital Statistics Report. Table 10. Number of deaths from 113 selected causes by age: United States 2005-2014. 2. Centers for Disease Control and Prevention (CDC). Fluview. Influenza-associated pediatric mortality. <https://gis.cdc.gov/GRASP/Fluview/PedFluDeath.html>. Accessed April 11-24, 2017.

During the past 2 influenza seasons in the United States²:

60% of children who died from the flu **WERE OTHERWISE HEALTHY**

80% of children who died from the flu **WERE NOT VACCINATED^c**

Influenza is a Leading Cause of Deaths in Seniors in the US

Adults 65+ years of age suffer disproportionately from influenza related morbidity and mortality¹⁻³:

Number of deaths for leading causes of death

- Heart disease: 614,348
- Cancer: 591,699
- Chronic lower respiratory diseases: 147,101
- Accidents (unintentional injuries): 136,053
- Stroke (cerebrovascular diseases): 133,103
- Alzheimer's disease: 93,541
- Diabetes: 76,488
- **Influenza and pneumonia: 55,227**
- Nephritis, nephrotic syndrome, and nephrosis: 48,146
- Intentional self-harm (suicide): 42,773

Source: [Health United States, 2015 Table 19](#) [PDF- 9.8 MB] (Data are for 2014)

15%
of the population



60%
of hospitalizations



and

90%
of deaths



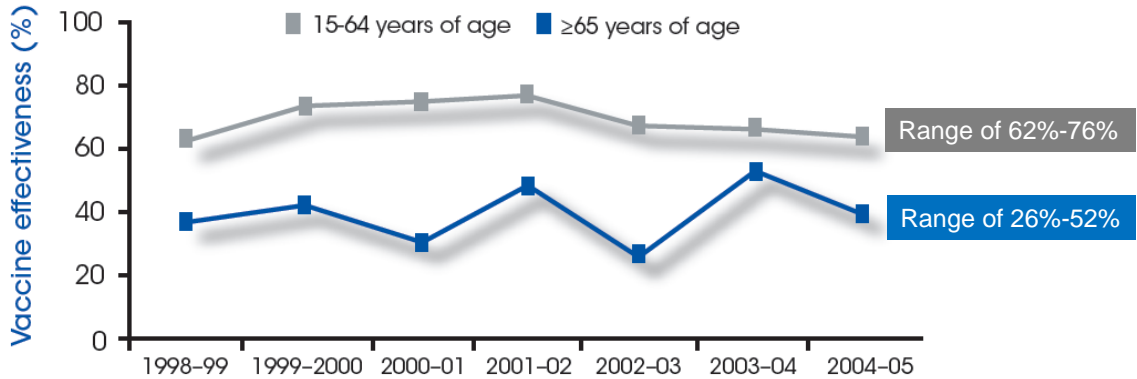
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References

1. Centers for Disease Control and Prevention (CDC). MMWR. 2009;58(RR-8):1-52. 2. Poland GA, Mulligan MJ. J Infect Dis. 2009;200:161-163. 3. Thompson WW, et al. JAMA. 2004;292(11):1333-1340.

Standard Influenza Vaccines Are Consistently Less Effective in Older Adults^{1,2}

Effectiveness of influenza vaccines in younger and older persons



Adapted from Monto AS, et al.¹

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References:

1. Monto AS, et al. *Vaccine*. 2009;27(37):5043-5053. 2. Legrand J, et al. *Vaccine*. 2006;24(44-46): 6605-6611.

Fluzone High-Dose Vaccine: Developed to Help Better Protect Seniors Against Influenza

Primary Endpoint^a

24.2%

MORE EFFICACIOUS
compared with Fluzone vaccine
against all flu strains^{1,2}

^a Laboratory-confirmed, protocol-defined, influenza-like illness caused by viral strains regardless of their antigenic similarity to vaccine components.

Secondary Endpoint^b

51.1%

MORE EFFICACIOUS
compared with Fluzone vaccine
against flu caused by similar
strains^{1,2}

^b Culture-confirmed influenza caused by viral types/subtypes antigenically similar to those contained in the respective annual vaccine formulations in association with a modified CDC-defined ILI



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References

1. Fluzone High-Dose vaccine [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc.; 2016. 2. DiazGranados et al, *N Engl J Med* 2014;371:635-645.

Improved Outcomes Demonstrated With High-Dose Vaccine in Studies Including Millions of 65+ Subjects Over Four Seasons

Study Description		Study Outcome – rVE% (95% CI) High-Dose vs. Standard dose				
Design Season, Predominant strain Publication author	Number of subjects	Influenza-like Illness	Hospital Admission			Death (Post Influenza Admission)
			Influenza	Pneumonia	Cardio- respiratory	
RCT 2011–12, H1N1 DiazGranados ^{1,3}	14,500	45.3 (7.0; 69.0) ^a		46.4 (15.9; 65.8)	13.7 (–3.8; 28.2)	–0.4 (–10.1; 8.5)
RCT 2012–13, H3N2 DiazGranados ^{1,3}	17,489	20.7 (4.4; 34.3) ^a		34.3 (3.1; 55.4)	21.0 (6.1; 33.5)	13.6 (5.1; 21.4)
RCT 2009–10, Pandemic H1N1 DiazGranados ⁴	9,172	12.6 (–140.5; 65.8)		34.0 (–25.0; 66.0)		
Observational 2012–13, H3N2 Izurieta ⁵	2,545,275	21.9 (15.0; 28.7) ^b	21.6 (16.1; 26.7) ^c			
Observational 2012–13, H3N2 Shay ⁶	2,722,909		22.1 (16.6; 27.3)			36.4 (9.0; 56.0)
Observational 2013–14, H1N1 Shay ⁶	3,385,503		12.7 (4.9; 19.9)			2.5 (–47.0; 35.0)

Abbreviations: RCT: randomized controlled trial; rVE: relative vaccine efficacy; CI: confidence interval
Notes: ^a Laboratory-confirmed influenza-like illness; ^b Probable influenza-like illness; ^c Includes influenza-related ED visits and hospitalizations
References: see slide 11

2017–18 US Influenza Season Communication Objectives

Children:

- Influenza is serious for kids of all ages, even those who are completely healthy
- Get them vaccinated



Seniors:

- Influenza is very serious, even deadly for seniors, especially those with chronic conditions
- Get vaccinated with a vaccine specifically designed for you and with proven superior protection



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Sanofi Pasteur's Legacy and Commitment to Influenza Prevention: 70 Years and Counting

- 2016–17 Season: Delivered 70 million doses to the US
 - 7 million unplanned doses after ACIP's LAIV recommendation change last June
 - 20 million doses of Fluzone High-Dose vaccine: 60% of 65+ influenza immunizations
- 2017–18 Season: Producing 70 million doses of Fluzone vaccines to help protect Americans of all ages
- Manufacturing is progressing well; investments continue to improve flexibility and delivery timing
 - Expanded filling capacity in 2016
 - Broke ground on 3rd US manufacturing facility in 2016
 - Simplified bulk antigen process in 2017



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Peer-Reviewed Published Studies of Fluzone High-Dose Relative Efficacy/Effectiveness (Slide 7)

1. DiazGranados CA, Dunning AJ, Kimmel M, Kirby D, Treanor J, Collins A, Pollak R, Christoff J, Earl J, Landolfi V, Martin E. Efficacy of high-dose versus standard-dose influenza vaccine in older adults. *New England Journal of Medicine*. 2014 Aug 14;371(7):635-45.
2. DiazGranados CA, Robertson CA, Talbot HK, Landolfi V, Dunning AJ, Greenberg DP. Prevention of serious events in adults 65 years of age or older: a comparison between high-dose and standard-dose inactivated influenza vaccines. *Vaccine*. 2015 Sep 11;33(38):4988-93.
3. DiazGranados CA, Dunning AJ, Robertson CA, Talbot HK, Landolfi V, Greenberg DP. Efficacy and immunogenicity of high-dose influenza vaccine in older adults by age, comorbidities, and frailty. *Vaccine*. 2015 Aug 26;33(36):4565-71.
4. DiazGranados CA, Dunning AJ, Jordanov E, Landolfi V, Denis M, Talbot HK. High-dose trivalent influenza vaccine compared to standard dose vaccine in elderly adults: safety, immunogenicity and relative efficacy during the 2009–2010 season. *Vaccine*. 2013 Jan 30;31(6):861-6.
5. Izurieta HS, Thadani N, Shay DK, Lu Y, Maurer A, Foppa IM, Franks R, Pratt D, Forshee RA, MaCurdy T, Worrall C. Comparative effectiveness of high-dose versus standard-dose influenza vaccines in US residents aged 65 years and older from 2012 to 2013 using Medicare data: a retrospective cohort analysis. *The Lancet Infectious diseases*. 2015 Mar 31;15(3):293-300.
6. Shay DK, Chillarige Y, Kelman J, Forshee RA, Foppa IM, Werneck YL, Lu Y, Ferdinands JM, Iyengar A, Fry AM, Worrall Izurieta HS. Comparative Effectiveness of High-Dose Versus Standard-Dose Influenza Vaccines Among US Medicare Beneficiaries in Preventing Postinfluenza Deaths During 2012–2013 and 2013–2014. *J Infect Dis* 2017.

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IMPORTANT SAFETY INFORMATION

IMPORTANT SAFETY INFORMATION FOR FLUZONE HIGH-DOSE VACCINE

Fluzone High-Dose vaccine should not be administered to anyone with a known hypersensitivity (eg, anaphylaxis) to any vaccine component, including egg protein, or to a previous dose of any influenza vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following previous influenza vaccination, the decision to give Fluzone High-Dose vaccine should be based on careful consideration of the potential benefits and risks.

The most common local and systemic adverse reactions to Fluzone High-Dose vaccine include pain, erythema, and swelling at the injection site; myalgia, malaise, and headache. Other adverse reactions may occur. Vaccination with Fluzone High-Dose vaccine may not protect all individuals.

INDICATION FOR FLUZONE HIGH-DOSE VACCINE

Fluzone High-Dose vaccine is indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B virus contained in the vaccine. Fluzone High-Dose vaccine is approved for use in persons 65 years of age and older.

Before administering [Fluzone High-Dose](#) vaccine, please see full Prescribing Information.

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