SANOFI PASTEUR INFLUENZA VACCINES

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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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It Has Been a Rough Season 'In the News'…

HEALTH

This Flu Season Is the Worst in Nearly a Decade

By DONALD G. McNEIL Jr. JAN. 26, 2018

The New York Times

Flu vaccines just 25% effective against worst strain this year, CDC says

Kim Painter, Special for USA TODAY Published 1:00 p.m. ET Feb. 15, 2018 | Updated 5:22 p.m. ET Feb. 15, 2018

USA TODAY

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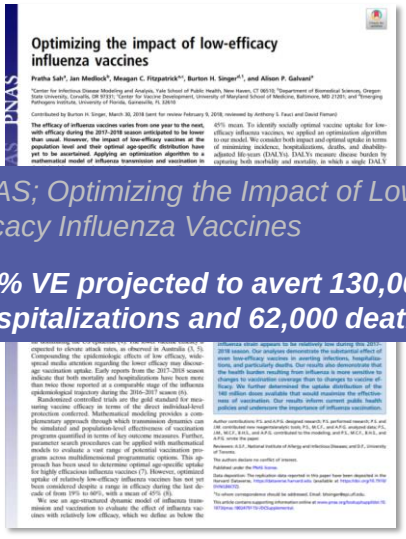
…but We Know the Current Vaccines Have a Major Impact


BRIEF REPORT

Modeling the Effect of Different Vaccine Effectiveness Estimates on the Number of Vaccine-Prevented Influenza-Associated Hospitalizations in Older Adults

CID; Modeling Effect of VE on Preventing Hospitalizations in 65+

40% VE would prevent 60,000 hospitalizations


Optimizing the impact of low-efficacy influenza vaccines

PNAS; Optimizing the Impact of Low-efficacy Influenza Vaccines

20% VE projected to avert 130,000 hospitalizations and 62,000 deaths

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And We Know there is Much More to Influenza than Influenza

The risk of having a heart attack is 6-10X greater after an influenza infection

Kwong, et al. *NEJM*
Warren-Gash, et al. *European Respiratory Journal*

Influenza vaccination is similarly effective in preventing heart attacks as statins, antihypertensive therapy, and smoking cessation

Meta-analysis - MacIntyre, et al. *Heart*

Adults with type 2 diabetes are less likely to be hospitalized for multiple conditions *(30% reduction in stroke, 22% reduction in heart failure)* or die *(24% reduction in all-cause death)* if they are vaccinated against influenza

Vamos et al. *CMAJ*

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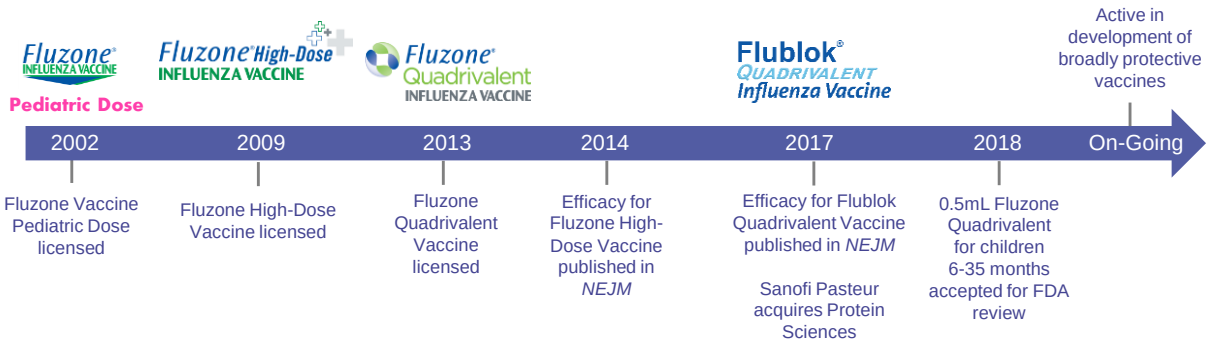
Sanofi Pasteur Committed to *Do More* and *Do Better* in the Fight Against Influenza



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Flublok Quadrivalent Vaccine is Demonstrated to Prevent More Influenza in Adults 50+

According to a study published in the *New England Journal of Medicine* in June 2017,

FLUBLOK QUADRIVALENT VACCINE PROVIDED:

30% **BETTER PROTECTION** from influenza disease

PRIMARY ENDPOINT: rtPCR[a]-confirmed, protocol-defined, influenza-like illness due to any influenza virus type or subtype

43% **BETTER PROTECTION** from influenza disease

SECONDARY ENDPOINT: Culture-confirmed, protocol-defined, influenza-like illness due to any influenza virus type or subtype

- First and only vaccine with demonstrated better protection for 50-64 population vs. standard-dose inactivated quadrivalent comparator
- Only recombinant hemagglutinin vaccine – replicates the wild-type HA exactly
- 3X the HA antigen of a standard-dose inactivated quadrivalent vaccine
- Comparable safety profile to standard-dose inactivated quadrivalent comparator

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Fluzone High-Dose Vaccine is Demonstrated to Prevent More Influenza and Reduce Serious Outcomes in Adults 65+

According to a head-to-head study published in the *New England Journal of Medicine* in August 2014 that spanned 2 flu seasons,[2] **FLUZONE HIGH-DOSE VACCINE PROVIDED**:

PRIMARY ENDPOINT

24.2% **BETTER PROTECTION** from influenza disease compared with Fluzone vaccine, when caused by viral strains regardless of their antigenic similarity to vaccine components

Primary endpoint of the study was the occurrence of laboratory-confirmed, protocol-defined, influenza-like illness caused by viral strains regardless of their antigenic similarity to vaccine components.

SECONDARY ENDPOINT

51.1% **BETTER PROTECTION** from influenza disease compared with Fluzone vaccine, when caused by viral strains similar to vaccine components

A secondary endpoint of the study was the occurrence of culture-confirmed influenza caused by viral types/subtypes antigenically similar to those contained in the respective annual vaccine formulations in association with a modified Centers for Disease Control and Prevention-defined influenza-like illness.

Study population: 31,803 adults ranging from 65 to 100 years of age (with a median age of 70 years)
[a]Per-protocol analysis set for efficacy assessments.

According to a recently published meta-analysis of 7 studies in *Expert Review of Vaccines*, Fluzone High-Dose demonstrated higher relative efficacy/effectiveness than standard-dose comparator vaccines:

Clinical Outcome	Pooled Relative Vaccine Efficacy/Effectiveness (95% CI)	*P*-value
All Studies (7 Observational + Randomized Studies)		
Influenza-like Illness	**18.3%** (7.0%, 28.3%)	0.002
Influenza Hospitalization	**17.8%** (8.1%, 26.5%)	<0.001
Pneumonia Hospitalization	**25.1%** (10.5%, 37.3%)	0.001
Cardiorespiratory Hospitalization	**18.2%** (6.8%, 28.1%)	0.002
All-cause Hospitalization	**9.9%** (1.3%, 17.7%)	0.025
Post-Influenza Mortality	**22.2%** (-18.2%, 48.8%)	0.240
All-cause Mortality	**2.5%** (-5.2%, 9.5%)	0.514
Randomized Studies Only (5)		
Influenza-like Illness	**24.1%** (10.0%, 36.1%)	0.002
Pneumonia Hospitalization	**27.3%** (15.3%, 37.6%)	<0.001
All-cause Hospitalization	**11.9%** (2.0%, 20.7%)	0.019
All-cause Mortality	**4.9%** (-6.5%, 15.1%)	0.381

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Sanofi Pasteur's Commitment for the 2018-19 Season

Do More

Producing nearly 70 million doses of Fluzone vaccines + Flublok Quadrivalent vaccine

Expanding / enhancing healthcare provider and patient education

- ***Senior Flu Shot* campaign**
- **Disease and vaccine education initiatives focused on children and adults 50+**

Do Better

Expanding availability and use of vaccines that help prevent more flu for adults 50+

- **Flublok Quadrivalent vaccine: 12-15X increase in availability**
- **Fluzone High-Dose vaccine: 2/3 of immunized seniors in 2017 and continuing to grow**

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IMPORTANT SAFETY INFORMATION FOR FLUBLOK QUADRIVALENT, FLUZONE QUADRIVALENT, AND FLUZONE HIGH-DOSE VACCINES

Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose vaccines should not be administered to anyone who has had a severe allergic reaction (eg, anaphylaxis) to any component (including egg protein for Fluzone Quadrivalent and Fluzone High-Dose vaccines) or previous dose of the respective vaccine. In addition, Fluzone Quadrivalent and Fluzone High-Dose vaccines should not be administered to anyone who has had a severe allergic reaction 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 Flublok Quadrivalent, Fluzone Quadrivalent, or Fluzone High-Dose vaccine should be based on careful consideration of the potential benefits and risks.

In adults, the most common local and systemic adverse reactions to Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose vaccines include pain at the injection site; headache and myalgia. In children, the most common reactions to Fluzone Quadrivalent vaccine include pain, erythema, and swelling at the injection site; myalgia, malaise, and headache (irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever in young children). Other adverse reactions to these vaccines may occur. Vaccination with Flublok Quadrivalent, Fluzone Quadrivalent, or Fluzone High-Dose vaccine may not protect all individuals.

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INDICATION FOR FLUBLOK QUADRIVALENT, FLUZONE QUADRIVALENT, AND FLUZONE HIGH-DOSE VACCINES

Flublok Quadrivalent, Fluzone Quadrivalent, and Fluzone High-Dose vaccines are indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B virus(es) contained in each vaccine. Flublok Quadrivalent vaccine is approved for use in persons 18 years of age and older. Fluzone Quadrivalent vaccine is approved for use in persons 6 months of age and older. Fluzone High-Dose vaccine is approved for use in persons 65 years of age and older.

Before administering Flublok Quadrivalent, Fluzone Quadrivalent, or Fluzone High-Dose vaccine, please see accompanying full Prescribing Information.

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