Fluzone® (Influenza Vaccine) Portfolio and Influenza Immunization Update

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Sanofi Pasteur believes in a world in which no one suffers or dies from a vaccine-preventable disease.
Influenza is a Leading Cause of Vaccine-Preventable Deaths in Children in the US

US pediatric\(^a\) deaths from vaccine-preventable diseases, 2005-2014\(^1\)

- Polio: 0
- Measles: 1
- Hepatitis: 20
- Pertussis: 149
- Meningitis\(^b\) Influenza: 220
- Total: 937

During the past 2 influenza seasons in the United States\(^2\):

- 60% of children who died from the flu WERE OTHERWISE HEALTHY
- 80% of children who died from the flu WERE NOT VACCINATED\(^c\)

\(^a\) ≤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.

References

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

Adults 65+ years of age suffer disproportionately from influenza related morbidity and mortality\(^1\)-\(^3\):

- Heart disease: 654,348
- Cancer: 591,699
- Chronic lower respiratory diseases: 147,101
- Accidents (unintentional injuries): 136,053
- Stroke (cerebrovascular diseases): 120,100
- Alzheimer's disease: 93,541
- Diabetes: 76,486
- Influenza and pneumonia: 55,227
- Nephritis, nephrotic syndrome, and nephrosis: 46,346
- Intentional self-harm (suicide): 42,773

Number of deaths for leading causes of death

15% of the population

15% of the population

60% of hospitalizations and 90% of deaths

References
Standard Influenza Vaccines Are Consistently Less Effective in Older Adults\textsuperscript{1,2}

Effectiveness of influenza vaccines in younger and older persons

![Graph showing vaccine effectiveness in younger and older persons]

Adapted from Monto AS, et al.\textsuperscript{1}

References:

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

**Primary Endpoint\textsuperscript{a}**

\textbf{24.2\%}

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

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

**Secondary Endpoint\textsuperscript{b}**

\textbf{51.1\%}

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

\textsuperscript{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

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

<table>
<thead>
<tr>
<th>Study Description</th>
<th>Number of subjects</th>
<th>Study Outcome – rVE% (95% CI) High-Dose vs. Standard dose</th>
<th>Hospital Admission</th>
<th>Death (Post Influenza Admission)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT 2011–12, H1N1</td>
<td>14,500</td>
<td>45.3 (7.0; 69.0)*</td>
<td>46.4 (15.9; 65.8)</td>
<td>13.7 (–3.8; 26.2)</td>
</tr>
<tr>
<td>RCT 2012–13, H3N2</td>
<td>17,489</td>
<td>20.7 (4.4; 34.3)*</td>
<td>34.3 (3.1; 55.4)</td>
<td>21.0 (6.1; 33.5)</td>
</tr>
<tr>
<td>RCT 2009–10, Pandemic H1N1</td>
<td>9,172</td>
<td>12.6 (–140.5; 65.6)</td>
<td>34.0 (–25.0; 66.0)</td>
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<tr>
<td>Observational 2012–13, H3N2</td>
<td>2,545,275</td>
<td>21.9 (15.0; 28.7)*</td>
<td>21.6 (16.1; 26.7)</td>
<td>36.4 (9.0; 56.0)</td>
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<tr>
<td>Observational 2012–13, H3N2</td>
<td>2,722,909</td>
<td>22.1 (16.6; 27.3)</td>
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</tr>
<tr>
<td>Observational 2013–14, H1N1</td>
<td>3,385,503</td>
<td>12.7 (4.9; 19.9)</td>
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</tbody>
</table>

Abbreviations: RCT: randomized controlled trial; rVE: relative vaccine efficacy; CI: confidence interval
Notes: * Laboratory-confirmed influenza-like illness; † Probable influenza-like illness; ‡ 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

SANOFI PASTEUR
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

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


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.