THE FIRST

RANDOMIZED, PRAGMATIC TRIAL

COMPARING 2 ENHANCED FLU VACCINES IN THE REAL WORLD*[1]

FLUAD influenza vaccine, adjuvanted

FLUAD® (Influenza Vaccine, Adjuvanted) VS **Fluzone® High-Dose** (Influenza Vaccine)

Clinical trials have demonstrated that FLUAD® produces a robust immune response[2]

- FLUAD met immunogenicity non-inferiority criteria compared to a non-adjuvanted, standard-dose influenza vaccine
- FLUAD has a demonstrated safety profile. The most common (≥10%) local and systemic reactions were myalgia, fatigue, headache, injection-site pain, and injection-site tenderness

*The quadrivalent formulations of the vaccines were used for the first season of the trial. The data of the quadrivalent formulations are relevant to the trivalent formulations, as both vaccines are manufactured using the same process and have overlapping compositions.

FLUAD® (Influenza Vaccine, Adjuvanted)

INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

FLUAD is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in adults 65 years of age and older.

This indication is approved under accelerated approval based on the immune response elicited by FLUAD. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer FLUAD to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

Please see Important Safety Information throughout and the full US Prescribing Information for FLUAD.

For US Healthcare Professional Use Only

CSL Seqirus

ROBUST STUDY DESIGN

Despite being preferentially recommended by the CDC for adults ≥65 years, FLUAD® (Influenza Vaccine, Adjuvanted) **and high-dose flu vaccines have never been compared head-to-head in a randomized pragmatic trial for the prevention of lab-confirmed influenza…until now.**[1]

Design

Large randomized, pragmatic trial evaluating the relative vaccine effectiveness of FLUAD compared to high-dose influenza vaccines for prevention of **PCR-confirmed influenza**[1]

- Randomization involved all facilities to use FLUAD or high-dose influenza vaccines on alternating weeks[1]
- The study is designed to test the hypothesis that FLUAD is non-inferior to high-dose influenza vaccine, with a non-inferiority margin of -20%[1]

Season

2023-2024 (results of second season to come, 2024-2025)[1]

Population

429,600 adults ≥65 years who are members of a large integrated healthcare delivery system within Northern California (anticipated total of 960,000 individuals with second season)[1]

Strengths

- The randomization combined with broad patient inclusion results in a more representative but still balanced study population compared to a typical clinical study[1]
- Lab-confirmed influenza is considered the "gold standard" for evaluating flu vaccine protection since it is the most specific[3]

Limitations

- Primary outcome did not include individuals who did not undergo PCR testing, which limits generalizability[4]
- Although the large healthcare system has a diverse population, it may not be representative of other populations in the US[4]

PCR=polymerase chain reaction

WARNINGS AND PRECAUTIONS

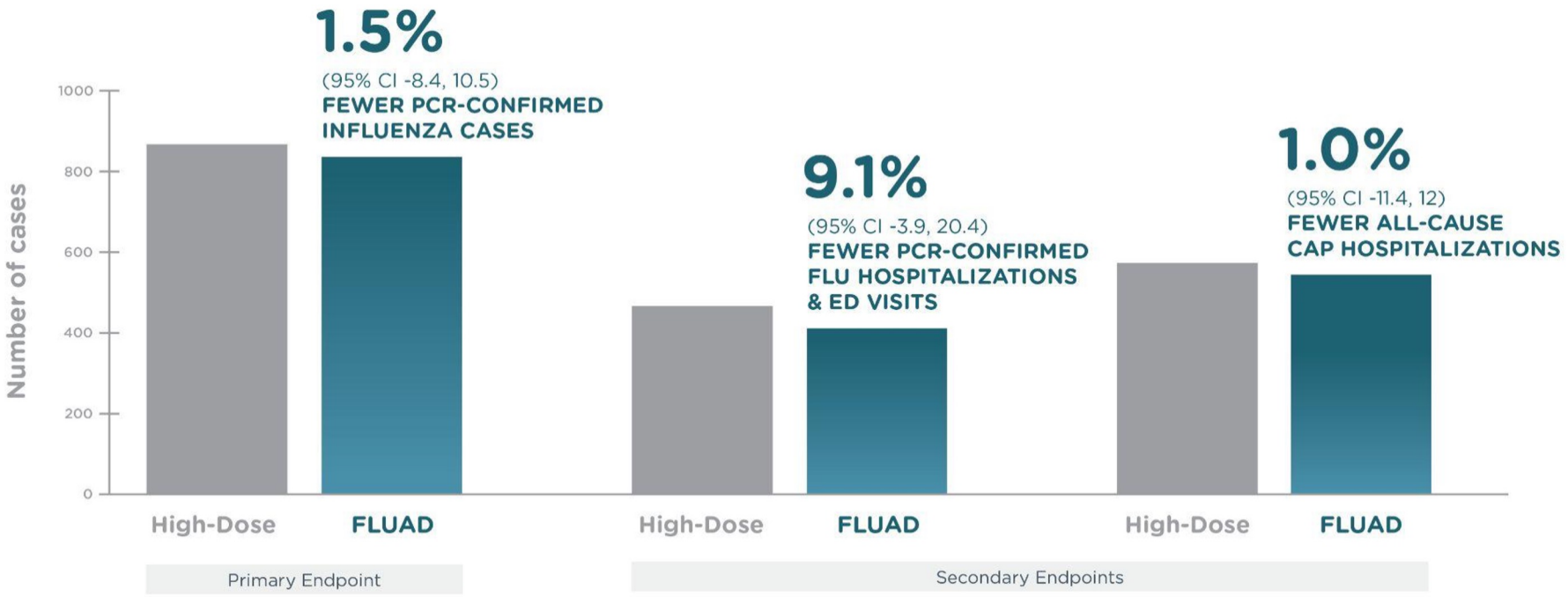
If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks.

Please see Important Safety Information throughout and the full US Prescribing Information for FLUAD.

REAL-WORLD RESULTS

First-season results comparing FLUAD (Influenza Vaccine, Adjuvanted) **vs high-dose influenza vaccines across a range of clinical outcomes*[1]**

Relative Vaccine Effectiveness, 2023-2024 Influenza Season[1]



*The quadrivalent formulations of the vaccines were used for the first season of the trial. The data of the quadrivalent formulations are relevant to the trivalent formulations, as both vaccines are manufactured using the same process and have overlapping compositions.

The outcomes reported in this study contain information not included in the Prescribing Information.
CAP=community-acquired pneumonia;
CI=confidence interval;
ED=emergency department;
PCR=polymerase chain reaction

WARNINGS AND PRECAUTIONS (continued)

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUAD.

Please see Important Safety Information throughout and the full US Prescribing Information for FLUAD.

PREFERENTIALLY RECOMMENDED FOR 65+

FLUAD® influenza vaccine, adjuvanted

These study results are consistent with ACIP's preferential recommendation of enhanced influenza vaccines—including FLUAD—for adults 65+[1]

Scan or click this link to access the full body of FLUAD RWE in adults 65+— including how FLUAD compares to high-dose influenza vaccines in antigenically mismatched seasons.

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Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD. Procedures should be in place to avoid injury from fainting.

The immune response to FLUAD in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals.

Vaccination with FLUAD may not protect all vaccine recipients against influenza disease.

ADVERSE REACTIONS

The most common (≥10%) local and systemic adverse reactions in adults 65 years of age and older who received FLUAD were injection site pain (25%), injection site tenderness (21%), myalgia (15%), fatigue (13%) and headache (13%).

Other adverse events may occur.

To report SUSPECTED ADVERSE REACTIONS, contact CSL Seqirus at 1-855-358-8966 or VAERS at 1-800-822-7967 and www.vaers.hhs.gov.

Before administration, please see the full US Prescribing Information for FLUAD.

References: 1. Klein N. Oral presentation presented at: IDWeek 2024 Meeting; October 16-19, 2024. Los Angeles, CA. **2.** FLUAD. Package insert. Seqirus Inc. **3.** Domnich A, et al. *Int J Infect Dis.* 2022;122:855-863. **4.** Hsiao A, et al. *N Engl J Med.* 2023;389(24):2245-2255.

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