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www.reachmd.com  
info@reachmd.com  
(866) 423-7849

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Immunization Against Influenza in Older Adults: Reviewing the ACIP Recommendations

### ReachMD Announcer:

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This medical industry feature, titled "Influenza Prevention in Older Adults: Reviewing the ACIP Recommendations" is sponsored by Seqirus. This program is intended for healthcare professionals.

Here's your host, Dr. Charles Turck.

### Dr. Turck:

Welcome to ReachMD. I'm Dr. Charles Turck, and joining me to share the rationale for the latest recommendations for influenza vaccination in older adults is Dr. Paul Hunter.

Dr. Hunter is an associate professor in the Department of Family Medicine and Community Health at the University of Wisconsin School of Medicine and Public Health in Madison. He's also a former ACIP voting member. Dr. Hunter, welcome to the program.

### Dr. Hunter:

Thank you for having me.

### Dr. Turck:

To start us off, Dr. Hunter, why are we particularly concerned about influenza in adults 65 and older?

### Dr. Hunter:

So this is a great starting point because it's really important to recognize that older adults are more susceptible to influenza infection—as well as increased severity of infection—than younger, healthier populations.<sup>1</sup> Influenza also increases the risk of hospitalization<sup>2</sup> and disability,<sup>3</sup> reduces the quality of life,<sup>3</sup> and increases mortality rate.<sup>4,5</sup> And the last thing we should keep in mind as we dive into our discussion is that adults 65 years and older experience morbidity and mortality caused by influenza more than any other age group.<sup>6</sup>

### Dr. Turck:

And with this burden in mind, are there vaccines available that can help prevent influenza in this aging population?

### Dr. Hunter:

Yes, so all influenza vaccines available in the United States—except for the live attenuated influenza vaccines—are licensed for use in adults aged 65 years and older.<sup>7</sup>

These include five standard-dose, unadjuvanted, inactivated vaccines; one high-dose inactivated vaccine; one adjuvanted inactivated vaccine; and one recombinant vaccine.<sup>7</sup>

Now adjuvanted and high-dose influenza vaccines, such as FLUAD® Quadrivalent and Fluzone® High-Dose Quadrivalent, are designed and licensed specifically for older adults,<sup>8,9</sup> but until recently, we didn't have any formal guidance on which types of flu vaccines are most effective in older adults.<sup>7</sup> And so back in 2019, the CDC's Advisory Committee on Immunization Practices, or ACIP for short, set out to see if they should update the recommendations based on the available data.

### Dr. Turck:

So with that being said, Dr. Hunter, what measures did the ACIP take to ultimately come up with their recommendations?

**Dr. Hunter:**

So the ACIP had the goal of answering the following policy question: Do the relative benefits and harms of higher-dose and adjuvanted vaccines, compared with one another and with other influenza vaccines, favor the use of any one or more of these vaccines over other age-appropriate options for people aged 65 years and older?<sup>10</sup>

To help answer this question, the ACIP's Influenza Work Group went through the GRADE process, which stands for Grading of Recommendations, Assessment, Development, and Evaluations.<sup>11</sup> GRADE is transparent framework designed to help develop and present summaries of evidence, so it provides a systematic approach for making clinical practice recommendations.<sup>11</sup>

During the GRADE process, ACIP looked at qualifying studies to see whether adjuvanted influenza vaccines or higher-dose vaccines serve as better options in this age group versus standard-dose influenza vaccines.<sup>10</sup> Specifically, the three vaccines looked at were FLUAD® Quadrivalent, Fluzone® High-Dose Quadrivalent, and Flublok® Quadrivalent.

ACIP focused on critical outcomes, including benefits like prevention of influenza illness, outpatient and ER visits, hospitalizations, and deaths; along with harms, including any solicited systemic adverse event with a severity grade greater than or equal to three and incidence of Guillain-Barré syndrome.<sup>10</sup>

Lastly, ACIP conducted an Evidence to Recommendations framework, or EtR for short, which included policy considerations beyond the clinical data of benefit versus risk.<sup>11</sup> This framework helps ensure that all important factors that determine a recommendation are considered and assessed in a transparent manner.

**Dr. Turck:**

So between the GRADE and EtR, Dr. Hunter, what kind of studies did the ACIP look at, and how many did they review?

**Dr. Hunter:**

Well, there were a lot of them. So the review team started with more than 10,000 studies, analyzed the full text of 3,500 of those, and ended up with 49 studies presented in the GRADE review at an ACIP meeting in February of 2022.<sup>12</sup>

These were peer-reviewed studies dating back to 1990 and included randomized studies, retrospective case-control and cohort studies, and prospective studies. They excluded things like case series without comparator information, animal studies, or any study which the entire population fell outside of the age range of 65 years and older.<sup>12</sup> They compared the adjuvanted influenza vaccine FLUAD® and higher-dose vaccines, Fluzone® high-dose and Flublok® with standard-dose influenza vaccines and with one another.<sup>10</sup>

**Dr. Turck:**

So what conclusions did the work group come to after reviewing the evidence? Let's start with the GRADE.

**Dr. Hunter:**

Okay. Overall, the GRADE showed evidence of benefit favoring adjuvanted and higher-dose influenza vaccines over standard-dose vaccines for older adults.<sup>10</sup> And importantly, there was no strong evidence favoring one over another in studies providing direct comparisons between these vaccines.<sup>10</sup> Now in terms of overall safety, no results favored one adjuvanted or higher-dose influenza vaccines over another, nor did they favor them over standard-dose vaccines.<sup>10</sup> And finally, limitations include that there were few randomized controlled trial data representing few influenza seasons, and there were no data reflecting current quadrivalent formulations, only the previous trivalent formulations.<sup>10</sup>

**Dr. Turck:**

And what about the Evidence to Recommendations? Can you walk us through those conclusions?

**Dr. Hunter:**

Sure, but before we dive in, I'd like to just remind everyone that the EtR framework didn't just look at benefits and harms; it also considered other domains such as public health importance, resource use, health equity, and feasibility.<sup>7</sup> The ACIP Influenza workgroup concluded that after working through the EtR that the desirable consequences of this recommendation would outweigh the undesirable consequences in most settings.<sup>7</sup>

Now with that being said, after reviewing the EtR framework in June of 2022, the ACIP voting members voted unanimously in favor of recommending that adults 65 years and older preferentially receive any of the adjuvanted or higher-dose influenza vaccines, meaning FLUAD® Quadrivalent, Fluzone® High-Dose Quadrivalent, or Flublok® Quadrivalent.<sup>13</sup> I'd like to point out that the large majority of patients 65 years and older already get adjuvanted or higher-dose influenza vaccines, so that patient acceptance and feasibility of

implementation in clinical settings is well-established.

If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.<sup>13</sup>

Don't miss a vaccination. This recommendation was published in CDC's Morbidity and Mortality Weekly Report in late August of 2022.

**Dr. Turck:**

Now we're almost out of time, Dr. Hunter, but in your opinion, what impact does this ACIP preferential recommendation have on our aging population?

**Dr. Hunter:**

Well, from a logistics point of view, having access to multiple vaccines is better because we're less concerned about supply issues. You don't want all of your eggs in one basket, and given our tight timeline for a vaccination, the more vaccines and vaccine options we have available, the more people in this population we can vaccinate, but perhaps most importantly, the ACIP preferential recommendation designates the use of these adjuvanted or higher-dose vaccines as the standard of care for older adults, which hopefully will improve equitable access to appropriate and more effective preventive care.

**Dr. Turck:**

A great comment for us to think on as we come to the end of today's program, and I want to thank my guest, Dr. Paul Hunter, for helping us better understand how the new ACIP preferential recommendations came to be. Dr. Hunter, it was great speaking with you today.

**Dr. Hunter:**

Thank you. It was a pleasure to be here.

**Dr. Turck:**

I'm Dr. Charles Turck. Before we close, let's take a moment to review some important safety information.

**ReachMD Announcer:**

**IMPORTANT SAFETY INFORMATION for FLUAD® (Influenza Vaccine, Adjuvanted) and FLUAD® QUADRIVALENT (Influenza Vaccine, Adjuvanted)**

### INDICATIONS AND USAGE

FLUAD® and FLUAD® QUADRIVALENT are inactivated influenza vaccines indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD® and FLUAD® QUADRIVALENT are approved for use in persons 65 years of age and older.

This indication is approved under accelerated approval based on the immune response elicited by FLUAD® and FLUAD® QUADRIVALENT. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Data demonstrating a decrease in influenza disease after vaccination with FLUAD® or FLUAD® QUADRIVALENT is not available.

### CONTRAINDICATIONS

Severe allergic reaction to any component of the vaccine, including egg protein, or after a previous dose of any influenza vaccine.

### WARNINGS AND PRECAUTIONS

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

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

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

Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD® and FLUAD® QUADRIVALENT. Ensure procedures are in place to avoid injury from falling associated with syncope.

### ADVERSE REACTIONS

FLUAD® administered by needle and syringe:

The most common ( $\geq 10\%$ ) local (injection site) adverse reactions observed in clinical studies were injection site pain (25%) and tenderness (21%).

The most common ( $\geq 10\%$ ) systemic adverse reactions observed in clinical studies were myalgia (15%), headache (13%), and fatigue (13%).

FLUAD® QUADRIVALENT administered by needle and syringe:

The most common ( $\geq 10\%$ ) local and systemic reactions in elderly subjects 65 years of age and older were injection site pain (16.3%), headache (10.8%) and fatigue (10.5%).

Other adverse events may occur. For a comprehensive list of local and systemic adverse reactions, please see full prescribing information.

To report SUSPECTED ADVERSE REACTIONS, contact Seqirus at 1- 855-358-8966 or VAERS at 1-800-822-7967 and [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

Before administration, please see the full [Prescribing Information](#) for FLUAD® or FLUAD® QUADRIVALENT.

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USA-FLUD-22-0050 December 2022