

Transcript Details

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Understanding 2019 CDC Recommendations for Pneumococcal Disease in Adults Ages 65+

Announcer Opening:

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The references for the information discussed today are available in the transcript which can be accessed on the site where you have listened to this podcast.

Here's your host, Margo Trueblood.

Host:

Welcome. Today, we'll be talking about the CDC's November 2019 pneumococcal disease recommendations for adults ages 65 and older.

With us is Dr. Javeed Siddiqui, an infectious disease physician and Chief Medical Officer at TeleMed2U in Roseville, California.

Dr. Siddiqui:

Happy to be here.

Host:

So, let's get right to it. What can you tell us about the 2019 update?

Dr. Siddiqui:

Well, the CDC recommendations discuss two pneumococcal vaccines that are available for use in adults ages 65 years and older in the United States.¹

Host:

But before we go any deeper, let's discuss indications and select safety information for one of those vaccines PNEUMOVAX 23, pneumococcal vaccine polyvalent.

Announcer:

PNEUMOVAX 23 is a vaccine indicated for active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine.

The serotypes included are 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F.

PNEUMOVAX 23 is approved for use in persons 50 years of age or older and persons ages 2 years and older who are at increased risk for pneumococcal disease. PNEUMOVAX 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.

Dr. Siddiqui:

So back to the recommendations. The CDC continues to recommend routine vaccination with PNEUMOVAX 23 for all appropriate adults ages 65 years and older.¹



In 2019, the CDC modified its recommendations for use of another pneumococcal vaccine in adults ages 65 years and older, called *Prevnar 13*, pneumococcal 13-valent conjugate vaccine. *Prevnar 13* is no longer recommended for routine administration to all immunocompetent adults in this age group.¹

Host:

Can you tell us a bit more about that change in the Prevnar 13 recommendations?

Dr. Siddiqui:

Sure, for *Prevnar 13*, the CDC recommends shared clinical decision-making for certain adults ages 65 years and older who have not previously received that vaccine. We'll talk more about this change in a bit.¹

Host:

Now, let's discuss some Select Safety Information for PNEUMOVAX 23, which you'll hear more of throughout this podcast.

Announcer:

Do not administer PNEUMOVAX 23 to individuals with a history of a hypersensitivity reaction to any component of the vaccine. Defer vaccination with PNEUMOVAX 23 in persons with moderate or severe acute illness. Use caution and appropriate care in administering PNEUMOVAX 23 to individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.

Since elderly individuals may not tolerate medical interventions as well as younger individuals, a higher frequency and/or a greater severity of reactions in some older individuals cannot be ruled out.

Persons who are immunocompromised, including persons receiving immunosuppressive therapy, may have a diminished immune response to PNEUMOVAX 23.

Host:

Can you help us better understand the November 2019 updates to the CDC recommendations for pneumococcal vaccination in adults ages 65 years and older? ¹

Dr. Siddiqui:

Yes. It's helpful to first talk about the history of the previous recommendations for this age group. Starting in the 1980s, the CDC has recommended PNEUMOVAX 23 for adults ages 65 years and older.²

In 2014, the CDC recommended routine vaccination with *Prevnar 13* for immunocompetent adults ages 65 years and older, followed sequentially by a routine dose of PNEUMOVAX 23.^{3,4} The CDC subsequently stated that the dose of PNEUMOVAX 23 should be given at least one year after the dose of *Prevnar 13*.^{3,4}

The CDC made these 2014 recommendations with the commitment to reevaluate the use of *Prevnar 13* in this population.¹ Since then, the CDC reevaluated direct and indirect effects of *Prevnar 13* in adults ages 65 years and older, given the remaining disease burden.¹

In November 2019, the CDC updated its recommendations for immunocompetent adults ages 65 years and older.¹

Host: Let's discuss the CDC's rationale for this change.

Dr. Siddiqui:

Sure. Since 2014, the CDC saw no population level impact on the incidence of invasive pneumococcal disease caused by *Prevnar 13* serotypes observed among adults ages 65 years and older. There was also no observed reduction in incidence of non-invasive pneumococcal pneumonia during this time.¹

As stated by the CDC's 2019 pneumococcal recommendations, routine vaccination with a single dose of PNEUMOVAX 23 continues to be recommended for all appropriate adults ages 65 years and older.¹

However, the use of Prevnar 13 in certain patients ages 65 years and older- specifically, those who do NOT have an immunocompromising condition, cerebrospinal fluid or CSF leak, or cochlear implant, and who have not previously received Prevnar 13

– is now based on shared clinical decision making. $^{1}\ensuremath{\text{Host:}}$

Could you talk a bit more about shared clinical decision-making?

Dr. Siddiqui:

Unlike a routine recommendation, shared clinical decision-making recommendations are individually-based and informed by a decision process between the health care provider and the patient.¹

When these patients and their vaccine providers engage in shared clinical decision-making about the option to use *Prevnar 13*, considerations may include the individual patient's risk of exposure to *Prevnar 13* serotypes and the risk for pneumococcal disease for that person as a result of underlying medical conditions.¹

Host:

Here is some additional safety information for PNEUMOVAX 23.

Announcer:

PNEUMOVAX 23 may not be effective in preventing pneumococcal meningitis in patients who have chronic CSF leakage resulting from congenital lesions, skull fractures, or neurosurgical procedures.

Host (Mid-Tag):

Thank you. As a reminder, you're listening to an industry feature titled "Addressing Pneumococcal Disease in Adults ages 65+: CDC 2019 Update"

Now Dr. Siddiqui, you wanted to discuss intervals for sequential administration if you decide to vaccinate appropriate immunocompetent patients ages 65 and older with *Prevnar 13*. Do I have that right?

Dr. Siddiqui:

That's right. For pneumococcal vaccine-naïve patients in this group who receive *Prevnar 13* based on shared clinical decision making, it is important for the patient to also receive 1 dose of PNEUMOVAX 23 at least 1 year later because PNEUMOVAX 23 remains routinely recommended for these patients.¹

PNEUMOVAX 23 and Prevnar 13 should not be coadministered.

Importantly, for immunocompetent adults in whom the 2014 sequential regimen was initiated with *Prevnar 13* but not yet completed with PNEUMOVAX 23, one dose of PNEUMOVAX 23 should be routinely administered at least 1 year after *Prevnar 13* was given.¹

Host:

Thanks, that information about an interval of at least 1 year when *Prevnar 13* is followed by PNEUMOVAX 23 in these patients is important. Is there anything more to think about for patients in this group who may have received PNEUMOVAX 23 before age 65?

Dr. Siddiqui:

For those who previously received PNEUMOVAX 23 before the age of 65 years, for example, those with certain chronic conditions such as diabetes, for whom PNEUMOVAX 23 is recommended, an additional dose of PNEUMOVAX 23 should be administered when they reach the age of 65, given at least 5 years after their first PNEUMOVAX 23 dose.¹

Again, the shared clinical decision making recommendation for *Prevnar 13* applies to immunocompetent adults ages 65 and older who do NOT have CSF leak or cochlear implant. There are different recommendations for other patients.

Host:

There are some important considerations regarding sequential administration. Correct?

Dr. Siddiqui:

Yes. Let's discuss them.

An immunogenicity study described in the Prescribing Information for *Prevnar 13* evaluated the sequential administration with PNEUMOVAX 23 in adults ages 60 to 64 years.⁵

That study observed a diminished immune response with one dose of PNEUMOVAX 23 followed by a dose of *Prevnar 13* one year later vs *Prevnar 13* alone. But it also observed a noninferior immune response with one dose of *Prevnar 13* followed by a dose of PNEUMOVAX 23 one year later vs PNEUMOVAX 23 alone.

A different immunogenicity study described in the Prescribing Information for PNEUMOVAX 23 evaluated sequential administration of *Prevnar 13* followed by PNEUMOVAX 23 in healthy adults ages 50 and older. Immune responses to shared serotypes were noninferior when the vaccines were given 8 weeks apart vs 26 weeks apart.

It's also important to remember a few additional points.

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The levels of antibodies that correlate with protection against pneumococcal disease have not been clearly defined.

Routine revaccination of immunocompetent persons previously vaccinated with a 23-valent vaccine is not recommended.

And, for subjects ages 65 years or older in a clinical study, systemic adverse reactions which were determined by the investigator to be vaccine-related were higher following revaccination with PNEUMOVAX 23 than following initial vaccination with PNEUMOVAX 23.

Host:

Thank you for that information. Let's shift gears and talk about serotypes. Could you tell us a little more about what serotypes are included in PNEUMOVAX 23?

Dr. Siddiqui:

PNEUMOVAX 23 contains 23 pneumococcal serotypes. Eleven of these serotypes are unique to PNEUMOVAX 23 and twelve are shared with *Prevnar 13*.

PNEUMOVAX 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.

Host:

Thank you. Let's again discuss some safety information for PNEUMOVAX 23.

Announcer:

The most common adverse reactions, reported in more than 10% of subjects vaccinated with PNEUMOVAX 23 for the first time in a clinical trial, were: injection-site pain, soreness, tenderness, injection-site swelling, induration, headache, injection-site erythema, asthenia and fatigue, and myalgia. Vaccination with PNEUMOVAX 23 may not offer 100% protection from pneumococcal infection.

Host:

Next, let's talk a bit about vaccination rates in people ages 65 and older.

Dr. Siddiqui:

Despite CDC recommendations for pneumococcal vaccination for adults ages 65 years and older, pneumococcal vaccination rates in this population remain suboptimal.

Based on a CDC analysis of certain pneumococcal vaccination claims submitted for reimbursement to the Centers for Medicare and Medicaid Services, as of September 2017, approximately 57% of adults ages 65 years and older had not received PNEUMOVAX 23, as recommended by the CDC.^{1,6}

Host:

Can you tell us about how the CDC analysis was conducted?

Dr. Siddiqui:

This was estimated pneumococcal vaccination coverage among adults ages 65 years and older, based on claims data for reimbursement by beneficiaries continuously enrolled in Medicare since reach age 65 from September 2009 through September 2017. The number of beneficiaries per annual enrollment ranged from 23.7 million to 25.2 million during these years. Adults were considered to be vaccinated with PNEUMOVAX 23 if a claim for pneumococcal vaccination was submitted at any time during their history of enrollment since reaching the age of 65 years.⁶

Host:

So that means only 43% of these people were vaccinated. Isn't that low? ⁶

Dr. Siddiqui:

It is. There's more work to do here.

We can make a positive impact for our patients by doing all we can today to help protect them against pneumococcal disease.

Host:

I want to thank my guest, Dr. Javeed Siddiqui, for helping us better understand pneumococcal disease and what the CDC recommends for adults from ages 65 and older. Dr. Siddiqui, it was great speaking with you today.

Dr. Siddiqui:

My pleasure.

Host:

I'm Margo Trueblood. Thanks for listening.

Announcer Close:

Before administering PNEUMOVAX 23, Pneumococcal Vaccine Polyvalent, please read the <u>Prescribing Information</u>, which can be accessed on the site where you have listened to this podcast. The <u>Patient Information</u> also is available.

The references for the information discussed today are available in the transcript, which also can be accessed on that site.

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References:

1. Matanock A, Lee G, Gierke R, et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged \geq 65 years: Updated recommendations of the Advisory Committee on Immunization Practices. *MMWR Morb Mortal Wkly Rep.* 2019;68(46):1069-1075.

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3. Kobayashi M, Bennett NM, Gierke R, et al. Intervals between PCV13 and PPSV23 vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep*. 2015;64(34):944-947.

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5. Prevnar 13 [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc; 2019.

6. CDC, AdultVaxView. Pneumococcal vaccination among US Medicare beneficiaries aged >65 years, 2009-2017. Accessed March 25, 2020. https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/pcv13-medicare-beneficiaries.html

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