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Influenza (Flu)

Vaccine Effectiveness: How Well Do the Flu Vaccines Work?

Questions & Answers

How effective is the flu vaccine?

CDC conducts studies each year to determine how well the influenza (flu) vaccine protects against flu illness. While vaccine effectiveness (VE) can vary, recent studies show that flu vaccination reduces the risk of flu illness by between 40% and 60% among the overall population during seasons when most circulating flu viruses are well-matched to the flu vaccine. In general, current flu vaccines tend to work better against influenza B and influenza A(H1N1) viruses and offer lower protection against influenza A(H3N2) viruses. See "Does flu vaccine effectiveness vary by type or subtype?" and "Why is flu vaccine typically less effective against influenza A H3N2 viruses?" for more information.

What are factors that influence how well the vaccine works?

How well the flu vaccine works (or its ability to prevent flu illness) can vary from season to season. The vaccine's effectiveness also can vary depending on who is being vaccinated. At least two factors play an important role in determining the likelihood that flu vaccine will protect a person from flu illness: 1) characteristics of the person being vaccinated (such as their age and health), and 2) the similarity or "match" between the flu viruses the flu vaccine is designed to protect against and the flu viruses spreading in the community. During years when the flu vaccine is not well matched to circulating influenza viruses, it is possible that little or no benefit from flu vaccination may be observed. During years when there is a good match between the flu vaccine and circulating viruses, it is possible to measure substantial benefits from flu vaccination in terms of preventing flu illness and complications. However, even during years when the flu vaccine match is good, the benefits of flu vaccination will vary, depending on various factors like the characteristics of the person being vaccinated, what influenza viruses are circulating that season and even, potentially, which type of flu vaccine was used.

Each flu season researchers try to determine how well flu vaccines work as a public health intervention. Estimates of how well a flu vaccine works can vary based on study design, outcome(s) measured, population studied and the season in which the flu vaccine was studied. These differences can make it difficult to compare one study's results with another's.

While determining how well a flu vaccine works is challenging, in general, recent studies have supported the conclusion that flu vaccination benefits public health, especially when the flu vaccine is well matched to circulating flu viruses. CDC uses mathematical modeling to estimate the burden of illness associated with influenza in terms of cases, hospitalizations and deaths. These figures are then used to assess the burden of illness averted by flu vaccines, i.e., how many influenza cases, hospitalizations and deaths are averted in the United States each year as a result of flu vaccination. An explanation of U.S. flu burden and burden averted by seasonal flu vaccines is available from CDC's Flu Burden page.

What are the benefits of flu vaccination?

There are many reasons to get an influenza (flu) vaccine each year. Below is a summary of the benefits of flu vaccination, and selected scientific studies that support these benefits.

- Flu vaccination can keep you from getting sick with flu.
  - Flu vaccine prevents millions of illnesses and flu-related doctor's visits each year. For example, during 2017-2018, flu vaccination prevented an estimated 6.2 million influenza illnesses, 3.2 million influenza-associated medical visits, 91,000 influenza-associated hospitalizations, and 5,700 influenza-associated deaths.
  - During seasons when the flu vaccine viruses are similar to circulating flu viruses, flu vaccine has been shown to reduce the risk of having to go to the doctor with flu by 40 percent to 60 percent.
- Flu vaccination can reduce the risk of flu-associated hospitalization for children, working age adults, and older adults.
  - Flu vaccine prevents tens of thousands of hospitalizations each year. For example, during 2017-2018, flu vaccination prevented an estimated 91,000 flu-related hospitalizations.
  - A 2014 study showed that flu vaccine reduced children's risk of flu-related pediatric intensive care unit (PICU) admission by 74% during flu seasons from 2010-2012.
  - In recent years, flu vaccines have reduced the risk of flu-associated hospitalizations among older adults on average by about 40%.
  - A 2018 study showed that from 2012 to 2015, flu vaccination among adults reduced the risk of being admitted to an intensive care unit (ICU) with flu by 82 percent.
- Flu vaccination is an important preventive tool for people with chronic health conditions.
  - Flu vaccination has been associated with lower rates of some cardiac events among people with heart disease, especially among those who had had a cardiac event in the past year.
  - Flu vaccination can reduce worsening and hospitalization for flu-related chronic lung disease, such as in persons with chronic obstructive pulmonary disease (COPD).
  - Flu vaccination also has been shown in separate studies to be associated with reduced hospitalizations among people with diabetes and chronic lung disease .
- Flu vaccination helps protect women during and after pregnancy.
  - Vaccination reduces the risk of flu-associated acute respiratory infection in pregnant women by about one-half.
  - A 2018 study that included influenza seasons from 2010-2016 showed that getting a flu shot reduced a pregnant woman's risk of being hospitalized with flu by an average of 40 percent.
  - A number of studies have shown that in addition to helping to protect pregnant women, a flu vaccine given during pregnancy helps protect the baby from flu for several months after birth, when he or she is not old enough to be vaccinated.
- Flu vaccine can be life-saving in children.
  - A 2017 study was the first of its kind to show that flu vaccination can significantly reduce a child's risk of dying from flu.
- Flu vaccination has been shown in several studies to reduce severity of illness in people who get vaccinated but still get sick.
  - A 2017 study showed that flu vaccination reduced deaths, intensive care unit (ICU) admissions, ICU length of stay, and overall duration of hospitalization among hospitalized flu patients.
  - A 2018 study showed that among adults hospitalized with flu, vaccinated patients were 59 percent less likely to be admitted to the ICU than those who had not been vaccinated. Among adults in the ICU with flu, vaccinated patients on average spent 4 fewer days in the hospital than those who were not vaccinated.
- Getting vaccinated yourself may also protect people around you, including those who are more vulnerable to serious flu illness, like babies and young children, older people, and people with certain chronic health conditions.

Is the flu vaccine effective against all types of flu and cold viruses?

Seasonal flu vaccines are designed to protect against infection and illness caused by the three or four influenza viruses (depending on vaccine) that research indicates will be most common during the flu season. "Trivalent" flu vaccines are formulated to protect against three flu viruses, and "quadrivalent" flu vaccines protect against four flu viruses. Flu vaccines do NOT protect against infection and illness caused by other viruses that also can cause flu-like symptoms. There are many other viruses besides flu viruses that can result in flu-like illness* (also known as influenza-like illness or "ILI") that spread during the flu season. These non-flu viruses include rhinovirus (one cause of the "common cold") and respiratory syncytial virus (RSV), which is the most common cause of severe respiratory illness in young children, and a major cause of severe respiratory illness in adults aged 65 years and older.

Does flu vaccine effectiveness vary by type or subtype?

Yes. The amount of protection provided by flu vaccines may vary by influenza virus type or subtype even when recommended flu vaccine viruses and circulating influenza viruses are alike (well matched). Since 2009, VE studies looking at how well the flu vaccine protects against medically attended illness have suggested that when vaccine viruses and circulating flu viruses are well-matched, flu vaccines provide better protection against influenza B or influenza A (H1N1) viruses than against influenza A (H3N2) viruses. A study [505 KB, 10 pages] that looked at a number of VE estimates from 2004-2015 found average VE of 33% (CI = 26%–39%) against illnesses caused by H3N2 viruses, compared with 61% (CI = 57%–65%) against H1N1 and 54% (CI = 46%–61%) against influenza B virus illnesses. VE estimates were lower when vaccine viruses and circulating viruses were different (not well-matched). The same study found pooled VE of 23% (95% CI: 2% to 40%) against H3N2 viruses when circulating influenza viruses were significantly different from (not well-matched to) the recommended influenza A(H3N2) vaccine component.

Why is flu vaccine typically less effective against influenza A(H3N2) viruses?

There are a number of reasons why flu vaccine effectiveness against influenza A(H3N2) viruses may be lower.

1. While all influenza viruses undergo frequent genetic changes, the changes that have occurred in influenza A(H3N2) viruses have more frequently resulted in differences between the virus components of the flu vaccine and circulating influenza viruses (i.e., antigenic change) compared with influenza A(H1N1) and influenza B viruses. That means that between the time when the composition of the flu vaccine is recommended and the flu vaccine is delivered, H3N2 viruses are more likely than H1N1 or influenza B viruses to have changed in ways that could impact how well the flu vaccine works.
2. Growth in eggs is part of the production process for most seasonal flu vaccines. While all influenza viruses undergo changes when they are grown in eggs, changes in influenza A(H3N2) viruses tend to be more likely to result in antigenic changes compared with changes in other influenza viruses. These so-called "egg-adapted changes" are present in vaccine viruses recommended for use in vaccine production and may reduce their potential effectiveness against circulating influenza viruses. Other vaccine production technologies, e.g., cell-based vaccine production or recombinant flu vaccines, circumvent this shortcoming associated with the use of egg-based candidate vaccine viruses in egg-based production technology, but CDC also is using advanced molecular techniques to try to get around this short-coming.

How effective is the flu vaccine in the elderly?

In numerous studies since 2010, flu vaccines have helped protect adults 65 years of age and older against influenza A(H1N1) viruses and both lineages of influenza B viruses. Specifically, flu vaccines have reduced the risk of medically attended illness caused by H1N1 or B by more than 60% on average among people age65 and older (1). Flu vaccines also have reduced the risk of flu hospitalization among adults age 65 and older by 54% against A(H1N1) viruses and by 31%

against influenza B viruses on average (2).

However, protection against influenza A(H3N2) flu viruses has been less consistent. On average, flu vaccines have reduced the risk of doctor visits with A(H3N2) flu by 24% and reduced the risk of hospitalization with A(H3N2) flu by 33% in adults age 65 and older (1,2). During seasons when the H3N2 vaccine component has been like (well-matched to) the flu viruses circulating in the community, the benefit from flu vaccination has been higher. During these seasons, flu vaccine reduced the risk of hospitalizations with A(H3N2) flu by 43% on average (2). But when the vaccine component was less similar to viruses in the community, the protection has dropped to 14% (2).

1. Edward A. Belongia, Danuta M. Skowronski, Huong Q. McLean et al. Repeated annual influenza vaccination and vaccine effectiveness: review of evidence. *Expert Review of Vaccines*. 2017 Jun; 16(7): 723-36. doi: 10.1080/14760584.2017.1334554.
2. Marc Rondy, Nathalie El Omeiri, Mark G. Thompson, et al. Effectiveness of influenza vaccines in preventing severe influenza illness among adults: A systemic review and meta-analysis of test-negative design case-control studies. Journal of Infection. Sept 2017; 65: 381-394. doi: 10.1016/j.jinf.2017.09.010

If older people have weaker immune responses to flu vaccination, should they still get vaccinated?

Despite the fact that some older adults (65 years of age and older) have weaker immune responses to the influenza A (H3N2) component of flu vaccines, there are many reasons why people in that age group should be vaccinated each year.

- First, people aged 65 and older are at increased risk of serious illness, hospitalization and death from the flu.
- Second, while the effectiveness of flu vaccines can be lower among some older people (particularly against influenza A(H3N2) viruses), there are seasons when significant benefit can be observed (this is particularly true against influenza A(H1N1) and influenza B viruses).
- Third, flu vaccine may protect against more serious outcomes like hospitalization and death. For example, one study concluded that one death was prevented for every 4,000 people vaccinated against flu (1).
- Flu vaccination has been shown in several studies to reduce severity of illness in people who get vaccinated but still get sick.
- In frail elderly adults, hospitalizations can mark the beginning of a significant decline in overall health and mobility, potentially resulting in loss of the ability to live independently or to complete basic activities of daily living. While the protection elderly adults obtain from flu vaccination can vary significantly, a yearly flu vaccination is still the best protection currently available against flu.
- Fourth, it's important to remember that people who are 65 and older are a diverse group and often are different from one another in terms of their overall health, level of activity and mobility, and behavior when it comes to seeking medical care. This group includes people who are healthy and active and have responsive immune systems, as well as those who have underlying medical conditions that may weaken their immune system and their bodies' ability to respond to vaccination. Therefore, when evaluating the benefits of flu vaccination, it is important to look at a broader picture than what one study's findings can present.

1. Fireman B, Lee J, Lewis N et al. Influenza vaccination and mortality: differentiating vaccine effects from bias. *Am J Epidemiol*. 2019 Sep; 170(5): 650-6. doi: 10.1093/aje/kwp173 .

How effective is the flu vaccine in children?

Vaccination has been found in most seasons to provide a similar level of protection against flu illness in children to that seen among healthy adults.

In several studies, flu vaccine effectiveness was higher among children who received two doses of flu vaccine the first season that they were vaccinated (as recommended) compared to "partially vaccinated" children who only received a single dose of flu vaccine. However, in some seasons, partially vaccinated children still receive some protection.

In addition to preventing illness, flu vaccine can prevent severe, life-threatening complications in children, for example:

- A 2014 study showed that flu vaccine reduced children's risk of flu-related pediatric intensive care unit (PICU) admission by 74% during flu seasons from 2010-2012.
- In 2017, a study in the journal *Pediatrics* was the first of its kind to show that flu vaccination also significantly reduced a child's risk of dying from the flu. The study, which looked at data from four flu seasons between 2010 and 2014, found that flu vaccination reduced the risk of flu-associated death by half (51 percent) among children with underlying high-risk medical conditions and by nearly two-thirds (65 percent) among healthy children.

How are benefits of vaccination measured?

Public health researchers measure how well flu vaccines work through different kinds of studies. In "randomized studies," flu vaccination is randomly assigned, and the number of people who get flu in the vaccinated group is compared to the number that get flu in the unvaccinated or placebo group. Randomized studies are the "gold standard" (best method) for determining how well a vaccine works. The effects of vaccination measured in these studies is called "efficacy." Randomized, placebo controlled studies are expensive and are not conducted after a recommendation for vaccination has been issued, as withholding vaccine from people recommended for vaccination would place them at risk for infection, illness and possibly serious complications. For that reason, most U.S. studies conducted to determine the benefits of flu vaccination are "observational studies."

"Observational studies" compare the occurrence of flu illness in vaccinated people compared to unvaccinated people, based on their decision to be vaccinated or not. This means that vaccination of study subjects is not randomized. The measurement of vaccine effects in an observational study is referred to as "effectiveness."

How does CDC present data on flu vaccine effectiveness?

CDC typically presents vaccine effectiveness (VE) as a single point estimate: for example, 60%. This point estimate represents the reduction in risk provided by the flu vaccine. CDC vaccine effectiveness studies measure two outcomes: laboratory confirmed flu illness that results in a doctor's visit or laboratory-confirmed flu that results in hospitalization. For these outcomes, a VE point estimate of 60% means that on average the flu vaccine reduces a person's risk of a flu outcome by 60%.

In addition to the VE point estimate, CDC also provides a "confidence interval" (CI) for this point estimate, for example, 60% (95% CI: 50%-70%). The confidence interval provides a lower boundary for the VE estimate (e.g., 50%) as well as an upper boundary (e.g., 70%). One way to interpret a 95% confidence interval is that if CDC were to repeat this study 100 times and calculate 100 confidence intervals, 95 times out of 100, the confidence interval would contain the true VE value. A simpler interpretation is that there is a 95% chance that the true VE lies within the confidence interval – therefore, there is still the possibility that five times out of 100 (a 5% chance) the true VE value could fall outside of the 50%-70% confidence interval.

Why are confidence intervals important for understanding flu vaccine effectiveness?

Confidence intervals are important because they provide context for understanding the precision or exactness of a VE point estimate. The wider the confidence interval, the less exact the point value estimate of vaccine effectiveness becomes. Take, for example, a VE point estimate of 60%. If the confidence interval of this point estimate is 50%-70%, then we can have greater certainty that the true protective effect of the flu vaccine is near 60% than if the confidence interval

was between 10% and 90%. Furthermore, if a confidence interval crosses zero, for example, (-20% to 60%), then the point value estimate of VE provided is "not statistically significant." People should be cautious when interpreting VE estimates that are not statistically significant because such results cannot rule out the possibility of zero VE (i.e., no protective benefit). The width of a confidence interval is related in part to the number of participants in the study, and so studies that provide more precise estimates of VE (and consequently, have a narrower confidence interval) typically include a large number of participants.

Is it true that getting vaccinated repeatedly can reduce vaccine effectiveness?

A recent report examining studies from 2010-11 to 2014-15 concluded that the effectiveness of a flu vaccine may be influenced by vaccination the prior season or during many prior seasons (1). In some seasons, protection against influenza A(H3N2) virus illness may have been lower for people vaccinated in the current season and the prior season compared to those who had only been vaccinated in the current season. This fits with findings on immune response to vaccination that suggest repeated influenza vaccination can weaken immune response to vaccination and especially to the H3N2 vaccine component. However, repeated annual vaccination also can be beneficial during some seasons, since sometimes people retain and carry over immune protection from one season to the next. During some seasons, people who missed getting vaccinated still had residual protection against influenza illness.

Information regarding flu vaccination history is particularly important to these types of evaluations, and can be difficult to confirm, as accurate vaccination records are not always readily available. People who choose to get vaccinated every year may have different characteristics and susceptibility to flu compared to those who do not seek vaccination every year. CDC thinks that these findings merit further investigation to understand the immune response to repeat vaccination. CDC supports continued efforts to monitor the effects of repeat vaccination each year. However, based on the substantial burden of flu in the United States, and on the fact that most studies point to vaccination benefits, CDC recommends that yearly flu vaccination remains the first and most important step in protecting against flu and its complications.

1. Edward A. Belongia, Danuta M. Skowronski, Huong Q. McLean et al. Repeated annual influenza vaccination and vaccine effectiveness: review of evidence. *Expert Review of Vaccines*. 2017 Jun; 16(7): 723-36. doi: 10.1080/14760584.2017.1334554.

Why are there so many different outcomes for vaccine effectiveness studies?

Vaccine effectiveness studies that measure different outcomes are conducted to better understand the different kinds of benefits provided by vaccination. Ideally, public health researchers want to know how well flu vaccines work to prevent illness resulting in a doctor visit, or illness resulting in hospitalization, and even death associated with the flu, to evaluate the benefits of vaccination against illness of varying severity. Because estimates of vaccine effectiveness may vary based on the outcome measured (in addition to season, population studied and other factors), results should be compared between studies that used the same outcome for estimating vaccine effectiveness.

How does CDC measure how well the vaccine works?

Scientists continue to work on better ways to design, conduct and evaluate non-randomized (i.e., observational) studies to assess how well flu vaccines work. CDC has been working with researchers at universities and hospitals since the 2003-2004 flu season to estimate how well flu vaccine works through observational studies using laboratory-confirmed flu as the outcome. These studies currently use a very accurate and sensitive laboratory test known as real-time RT-PCR (reverse transcription polymerase chain reaction) to confirm medically-attended flu virus infections as a specific outcome. CDC's studies are conducted in five sites across the United States to gather more representative data. To assess how well the vaccine works across different age groups, CDC's studies of flu vaccine effects have included all people aged 6 months

and older recommended for an annual flu vaccination. Similar studies are being done in Australia, Canada and Europe. More recently, CDC set up a second network, called the Hospitalized Adult Influenza Vaccine Effectiveness Network (HAIVEN), that looks at how well flu vaccine protects against flu-related hospitalization among adults aged 18 and older.

What do recent vaccine effectiveness studies show?

Recent studies show flu vaccine can reduce the risk of flu illness by between 40% and 60% among the overall population during seasons when most circulating flu viruses are well matched to the flu vaccine viruses.

Do recent vaccine effectiveness study results support flu vaccination?

The large numbers of flu-associated illnesses and deaths in the United States, combined with the evidence from many studies that show flu vaccines help to protect against flu illness and its potentially serious complications, support the current U.S. flu vaccination recommendations.

Where can I get more information?

CDC has compiled a list of selected publications related to vaccine effectiveness.

Besides vaccination, how can people protect themselves against the flu?

Getting a flu vaccine each year is the best way to prevent the flu. In addition to getting the flu shot, people should take the same everyday preventive actions to prevent the spread of flu, including covering coughs, washing hands often, and avoiding people who are sick. Antiviral drugs are an important second line of defense to treat the flu. These drugs are not a substitute for vaccination and must be prescribed by a health care provider.

More information on Vaccine Selection.

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