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Inside

**First Self-Administered Flu Vaccine
Approved by US FDA**

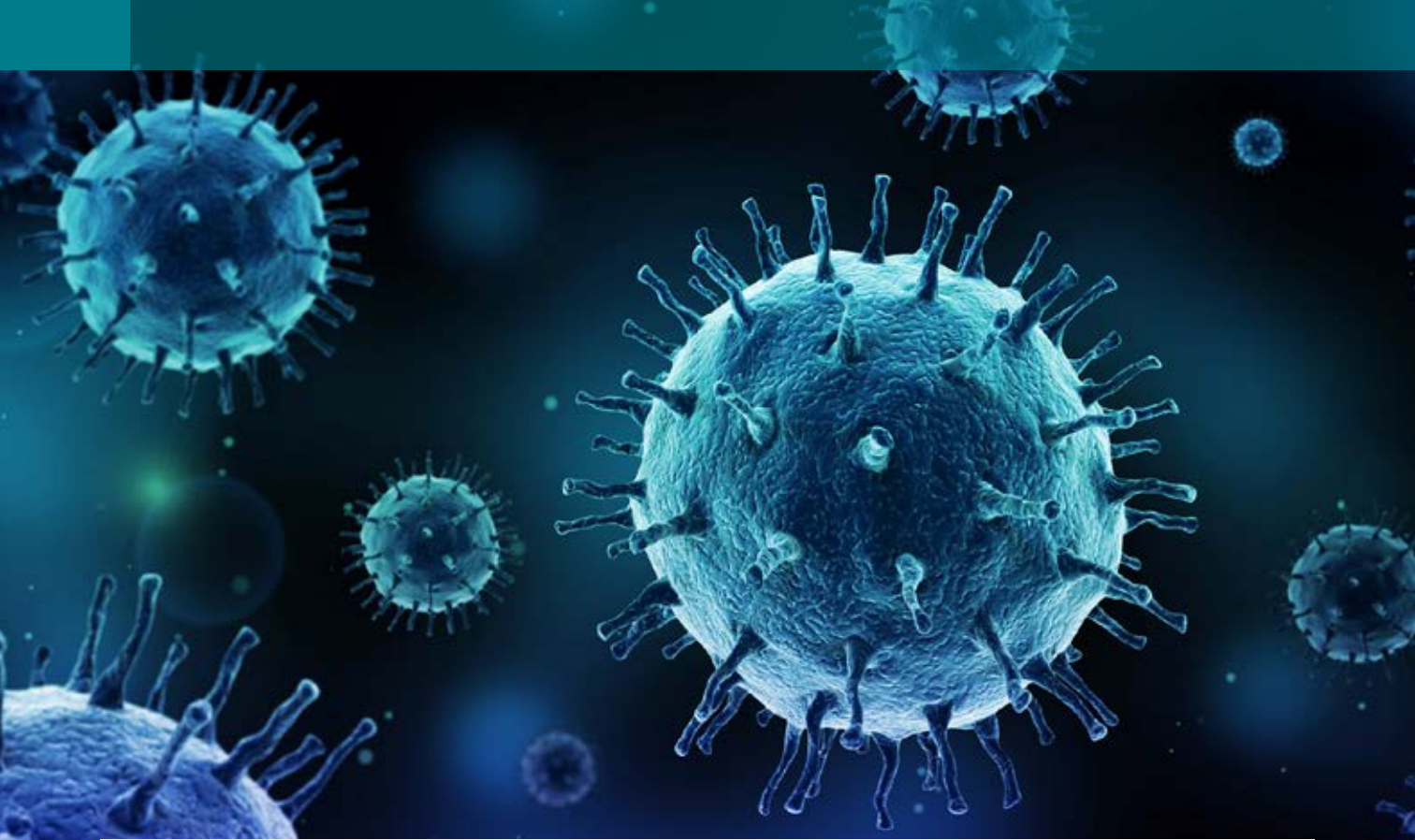
PAGE 2

**US Pertussis Cases Have Increased
Nearly 5-Fold During 2024,
According to the CDC**

PAGE 3

**Long COVID Risk Declined
Over the Pandemic and Vaccination
Was Key, But Risk Remains**

PAGE 4



First Self-Administered Flu Vaccine Approved by US FDA

By **Sydney Jennings**

The first influenza vaccine that does not require administration by a health care professional has been approved by the US FDA. FluMist (influenza vaccine live, intranasal; AstraZeneca) received the stamp of approval September 20 for self- or caregiver-administration, according to an FDA news release.

“[The] approval of the first influenza vaccine for self- or caregiver-administration provides a new option for receiving a safe and effective seasonal influenza vaccine potentially with greater convenience, flexibility, and accessibility for individuals and families,” Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research, said in the news release.

The intranasal vaccine was

“[The] approval of the first influenza vaccine for self- or caregiver-administration provides a new option for receiving a safe and effective seasonal influenza vaccine potentially with greater convenience, flexibility, and accessibility for individuals and families.”

already approved for the prevention of influenza caused by subtypes A and B in individuals aged 2 to 49 years. Individuals can still receive the vaccine from a health care professional in a health care setting, including the pharmacy, or administer it themselves or via a caregiver aged 18 years and older. Those who choose self- or caregiver-administration will receive the vaccine from a third-party online pharmacy, along with instructions for use and storage, administration, and disposal.

The FDA’s decision comes after a supplemental biologics license application (sBLA) was submitted by AstraZeneca in October 2023. The sBLA was supported by a usability study confirming the vaccine’s feasibility. ■

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US Pertussis Cases Have Increased Nearly 5-Fold During 2024, According to the CDC

By **Grace Halsey**

Pertussis cases have increased by nearly 5-fold in the US since 2023, according to the most recent data reported from the CDC. Across the US there have been 18,506 cases through the week ending October 12, compared with 4,157 cases through the same reporting period last year.¹

Case numbers trended lower than usual over the course of the COVID-19 pandemic and have since the end of the public health emergency, but the country appears to be returning to a more typical pre-pandemic pattern where more than 10,000 cases are reported annually. The number this year, however, surpasses that seen at the same time in 2019, prior to the COVID-19 pandemic, the agency said.¹

The CDC attributes the surge to converging factors that include the end of pandemic infection mitigation measures, eg, masking and remote learning, which likely reduced transmission rates, and the natural waning in vaccine protection.¹

“As typical infection patterns return to the United States, CDC expects pertussis cases to increase both in unvaccinated and vaccinated populations. Pertussis occurs in vaccinated people since protection from vaccination fades over time,” the CDC website states.¹

Pertussis, also referred to as whooping cough, is highly contagious, and early symptoms often resemble a common cold. However, the cough, which can be severe, can last for weeks or even months. Symptom onset is typically within 5 to 10 days of exposure, although latency of up to 3 weeks is possible.²

People of all ages are susceptible to pertussis, according to the CDC;

Pertussis is a nationally notifiable disease, and the CDC requests that health care professionals notify the appropriate health department of all patients with suspected pertussis.

age and underlying medical conditions increase the risk for severe disease. Infants younger than 1 year are at the greatest risk for contracting the infection and also for developing severe complications. Among those at risk of their condition worsening if infected with pertussis are individuals who are immunocompromised or have moderate to severe asthma.²

Infected persons can spread the *Bordetella pertussis* bacteria from the time symptoms first appear and for 2 weeks or longer after the cough begins. Importantly, symptoms may be mild for some people, so mild they may not be aware they have the infection. In fact, infants and toddlers may be infected by older siblings, parents, or caregivers who are unaware they are sick. The CDC recommends vaccination against pertussis for all age groups.²

Waning protection

Research on the durability of immunity from pertussis following the DTaP series in children has found nearly all are protected against illness within 1 year of the last shot and that 7 in 10 remain protected at 5 years post vaccination.³ The other 3 in 10 at this stage retain partial protection. For immunity from the Tdap shot, the pertussis component affords full protection for 70% of people during the first year and for approximately 30% to 40% four years later.³

Any adult who has not been vaccinated against pertussis should get a single dose of Tdap and then receive a booster shot every 10 years, the CDC says. Adults with Medicare drug

coverage are eligible to receive the vaccine free of charge.³

Vaccination during pregnancy

Infants younger than 1 year continue to have the highest reported rate of pertussis infection, according to the CDC, and mortality is highest before neonates are eligible for DTaP vaccination at age 2 months. There are 2 Tdap vaccine formulations approved for administration to pregnant women, with optimal timing recommended between 27- and 36-weeks' gestation and preferably during the early part of this period.⁴ Only 1 shot is recommended. The passive immunity from the mother helps protect the infant during the vulnerable early weeks before the first DTaP vaccination can be given. The CDC estimates that Tdap vaccination during pregnancy protects more than 3 in 4 neonates from infection with *B. pertussis* and up to 90% from hospitalization with pertussis.⁴ ■

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Long COVID Risk Declined Over the Pandemic and Vaccination Was Key, But Risk Remains

By **Grace Halsey**

The risk of developing long COVID appears to have decreased substantially over the course of the COVID-19 pandemic, according to a large analysis led by researchers from Washington University School of Medicine in St Louis, Missouri.¹

Researchers attributed approximately 70% of the risk reduction to vaccination against COVID-19 and 30% to the evolving characteristics of the virus as new strains emerged and to improved detection and management of the SARS-CoV-2 infection. But while the news is good on its face, study authors say the risk is still real.¹

The study, published in the *New England Journal of Medicine* on July 17, compared health records from the US Department of Veterans Affairs for 441,583 veterans with SARS-CoV-2 infection between March 2020 and January 31, 2022, and 4,748,504 uninfected controls. Investigators, led by Ziyad Al-Aly, MD, director of the Clinical Epidemiology Center and chief of

the research and education services at the VA St Louis Health Care System, looked specifically at the rates of long COVID one year after virus infection during 3 phases of the pandemic: predelta (before vaccines were available), the domination of the delta variant, and the period of the omicron variant (beginning December 2021).

Al-Aly and colleagues reported the cumulative incidence of long COVID at 1-year post infection decreased from a high of 10.42 cases per 100 persons among unvaccinated participants during the pre-delta era to a low of 3.50 cases per 100 persons among vaccinated individuals during the later omicron era.

Looking more closely at vaccinated vs unvaccinated individuals by variant era, 10.42 out of 100 developed long COVID one year after infection in the early pandemic months, before vaccines were available. With the arrival and tenure of the delta variant (June 19, 2020, through December 18, 2021) slightly fewer unvaccinated people (9.51 out of 100) received a long COVID diagnosis, but just slightly more than half that many who were vaccinated

(5.34 out of 100) were diagnosed a year after infection resolved. In the omicron era (began December 19, 2021) long COVID was diagnosed in 7.76 out of 100 unvaccinated people but only in 3.5 out of 100 vaccinated individuals.

The cumulative incidence of long COVID at 1 year was lower per 100 people among vaccinated compared with unvaccinated persons (average difference across delta and omicron eras, -4.22 events).

When they conducted decomposition analyses of the change in cumulative incidence of long COVID over the study period, the team found there were 5.23 fewer long COVID diagnoses per 100 persons 1-year post infection during the omicron era than during the predelta and delta eras combined. Al-Aly and colleagues calculated that 28.11% of the decrease could be attributed to variant characteristics during each era while the remainder of the difference, 71.89%, was related to the effect of vaccines.

“These findings suggest that vaccine uptake will be key to maintaining the lower cumulative incidence of

“These findings suggest that vaccine uptake will be key to maintaining the lower cumulative incidence of PASC [postacute sequelae of severe acute respiratory syndrome] relative to earlier phases of the pandemic.”

PASC [postacute sequelae of severe acute respiratory syndrome] relative to earlier phases of the pandemic,” the team wrote. However, Al-Aly also emphasized that even with the overall decline, the lowest rate of long COVID among vaccinated individuals, 3.5%, remains a substantial risk. “That’s 3 to 4 vaccinated individuals out of 100 getting long COVID,” he said. “Multiplied by the large numbers of people who continue to get infected and reinfected, it’s a lot of people. This remaining risk is not trivial. It will continue to add an already staggering health problem facing people across the world.”²

“We need to double down on our efforts to understand it so we can prevent suffering and treat affected individuals.”²

The CDC estimates that 6.4% of US adults have experienced long COVID, with prevalence ranging from 1.9% to as high as 10.6% across the country.³ Symptoms can be lingering versions of those experienced during the acute infection or can be altogether new; temporally they can follow resolution of the infection immediately or emerge weeks or even months after what appears to be recovery from the acute illness. The symptoms range from irritating to debilitating and manifest in persons whose infection was mild or even asymptomatic in addition to those who were hospitalized and critically ill.⁴

Research to date has documented more than 200 symptoms associated with long COVID, the most familiar

of those including fatigue, postexertional malaise, heart palpitations, blood clots, hair loss, persistent cough, loss of lung function, muscle pain and joint aches, brain fog, headache, depression, anxiety, sleep disturbances, loss of smell, and gastrointestinal problems.⁵

Individuals who have had COVID-19 may also be more likely to develop new health conditions including diabetes, cardiovascular disease, blood clots, and neurologic disorders.⁴

Among the study’s limitations, Al-Aly et al note that the homogeneity of the VA population, ie, older White men, may preclude generalization of the findings to other groups; also, the observational nature invites residual confounding and misclassification bias.¹ ■

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