Pfizer Bivalent COVID Booster Does Not Lead to Stroke: Health Canada

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In the middle of January, the United States' Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) released a statement that they will be investigating the safety of the Pfizer-BioNTech Bivalent COVID-19 booster dose (source).

The CDC's vaccine safety surveillance system signalled that there might be a link between this booster dose and ischemic stroke for people ages 65 and older (source).

A rapid-response investigation of the signal sparked the question: Are people 65 and older more likely to have an ischemic stroke in the 21 days after receiving the Pfizer-BioNTech Bivalent COVID-19 booster compared to days 22-42 after vaccination? (source)

The same statement emphasizes that **the CDC continues to recommend that everyone stays up-to-date with COVID-19 vaccination, including bivalent vaccines** (source).

Background Information

A booster dose or booster shot is a COVID-19 vaccine that you can get after you have received your first and second dose (source). Booster doses increase the protection you got from the first and second doses that may have decreased over time (source). Booster doses improve your protection against severe outcomes and may also help to reduce the risk of getting Long COVID, also known as Post-COVID Condition (source).

Bivalent COVID-19 vaccines are recommended for your booster dose (source). They're approved for those 5 years of age and older (source). The Pfizer-BioNTech bivalent booster Comirnaty® COVID-19 vaccine provides protection from the original strain of COVID-19 and the Omicron BA.4/BA.5 subvariants (source).

According to Health Canada's website, an ischemic stroke is the most common type of stroke (source, source). It involves a sudden loss of brain function triggered by a sudden brain blood vessel blockage (source, source). This can be caused by a variety of reasons, including smoking, high blood pressure, obesity, diabetes and high blood cholesterol, a sedentary lifestyle, and diet low in fruits and vegetables (source, source).

What is the signal signalling?

The FDA and CDC explained that "Often these safety systems detect signals that could be due to factors other than the vaccine itself. All signals require further investigation and

confirmation from formal epidemiologic studies. When one system detects a signal, the other safety monitoring systems are checked to validate whether the signal represents an actual concern with the vaccine" or not (source).

The statement shares that "no other safety systems have shown a similar signal and multiple subsequent analyses have not validated this signal" (source).

The CDC thinks that "it is very unlikely that the signal… represents a true clinical risk," but they want to be transparent that they did receive a signal, and they will investigate it further (source). The CDC and FDA will continue to evaluate additional data from these and other vaccine safety systems (source).

Is there any news on this?

Remember, this statement was published in mid-January. Last Thursday, the CDC gave an update: As part of the further investigation, scientists compared people 65 years and older who got the Pfizer bivalent booster to people in that age range who did not get the Pfizer bivalent booster within 22 to 42 days (source).

The results of the study found that, between the two groups of people 65 years and older, the ones who got the Pfizer bivalent booster had a 24% lower chance of experiencing an ischemic stroke 22-42 days after receiving the booster (Adjusted Rate Ratio = 0.76, source, slide 19). This study suggests that, in the real world, there is a reduced rate of ischemic strokes in that time period (source).

Other studies suggested that the rates of ischemic strokes in the 22-42 day time period "were lower than expected", which is promising (source, slide 23). The CDC will continue to monitor this issue and other possible explanations for what prompted the signal, such as the link between people who received the COVID-19 mRNA bivalent booster and the flu vaccine on the same day (source, slide 27).

What do Canadian Public Health Agencies have to say about this?

Last week, Health Canada (HC) and the Public Health Agency of Canada (PHAC) emailed Global News to say that there is currently "no indication" connecting mRNA bivalent vaccines with ischemic strokes (source).

The agency also said that as of January 1, 2023, over seven million mRNA bivalent vaccines have been given in Canada, and HC and the PHAC "have not observed an elevated risk or any signals for thromboembolic events or vascular events" after these vaccines were given (source).

The statement added that the possible link between bivalent Pfizer shots and strokes in older adults has not been observed by any other international regulatory services to date, either (source).

In Canada, less than five reports of ischemic stroke have been submitted to PHAC and HC to date after receiving an mRNA bivalent booster, and of those, "only one followed the Pfizer-BioNTech bivalent vaccine" that was for "an individual aged 65 years or older" (source).

"Health Canada and PHAC continue to monitor the safety of COVID-19 vaccines approved in Canada to ensure that their benefits continue to outweigh their risks, as is done for all approved vaccines in Canada," said the email (source).

At the time of writing, these agencies have not published an official statement saying this.

Final Thoughts

Last week, PHAC confirmed that, since the beginning of the COVID-19 pandemic nearly three years ago, over 50,000 Canadians have died after contracting COVID-19 (source, source).

The United States' CDC and FDA and Canada's HC and PHAC all agree that this signal should not change anybody's decision to get a Pfizer bivalent booster dose (source, source).

Even so, the issue is being taken seriously and investigated thoroughly (source). The studies that have been done so far suggest that people 65 and older are not more likely to have an ischemic stroke after receiving the Pfizer-BioNTech Bivalent COVID-19 booster (source).

If you have any questions about vaccine safety, here are some options:

1. You can book a phone appointment with the VaxFacts Clinic to speak with a trusted physician from the Scarborough Health Network at www.shn.ca/vaxfacts or 416-438-2911 ext. 5738. This line is not just for people in Scarborough; it's for everyone in Canada. This service is available in over 200 languages. If you are Black and would like to speak to a Black doctor, just let them know, and they will connect you with one.
2. You can speak to your family healthcare provider, such as your family doctor.
3. If you don't have one, you can call the Provincial Vaccine Contact Centre at 1-833-943-3900 to speak to a health specialist. (TTY for people who are deaf, hearing-impaired or speech-impaired: 1-866-797-0007). This line is available in more than 300 languages, seven days a week from 8:00 a.m. to 8:00 p.m.
4. You can always contact your local public health unit. To find your public health unit, click here. (source)

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If you think you may be experiencing symptoms of COVID-19, take the self-assessment at www.ontario.ca/coronavirus. Follow all directions from your medical provider or your local health unit at the following phone numbers:

Health Connect Ontario: 811

Telehealth Ontario: 1-866-797-0000

Toronto Public Health: 416-338-7600

Peel Public Health: 905-799-7700

Durham Region Health Department: 905-668-7711

York Region Public Health: 1-877-464-9675