Bivalent Vaccines, Explained July 29, 2022

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Ontario's seventh wave of COVID-19 is also its third wave that has been driven by the Omicron variant and its sub-variants.* According to the most recent data from Public Health Ontario, 99.9% of cases in the province are either the Omicron variant or one of its many sub-variants (page 5).

The currently-available COVID-19 vaccines and booster doses were designed to provide immunity against the original version of the COVID-19-causing virus that was spreading in late 2019.* After these vaccines were developed, variants such as Omicron (and its sub-variants) mutated to be more resistant to them.*

As a result, it's common to be fully vaccinated and still get infected with Omicron.* For many people with disabilities and people with certain health conditions, being infected can lead to severe health outcomes.* This is partly why many people have called for the formulas of booster doses to be updated to provide better protection from these variants.*

What are bivalent vaccines?

Keep in mind that "mono" means "one" and "bi" means "two". So a <u>mono</u>valent vaccine protects against the original version of the virus (also called "the original strain"), and a <u>bi</u>valent vaccine protects against multiple viruses, including any variants of a particular virus. The bivalent COVID-19 boosters that will be discussed in this article contain the vaccine for the original version as well as another vaccine for the Omicron variant.

Infectious disease specialist Dr. Zain Chagla describes it like this:

"In essence, <u>bivalent</u> vaccines are a split between the old 'original' mRNA sequence and the new sequence. So for example, Moderna's bivalent is 25 micrograms of the old vaccine, 25 micrograms of the updated vaccine."

Is it safe to have two vaccines in one dose?

During this time last year, many people were concerned about vaccine mixing, i.e., getting vaccines from different companies (e.g., Pfizer-BioNTech, Moderna, and AstraZeneca) for their first and second dose.

We can say with certainty that mixing brands of COVID-19 vaccines is both safe and effective for most people.**,* In fact, it's been proven to improve your body's immune response to fighting the virus.**,*

Bivalent vaccines are a mix of two vaccines from the same brand in one dose, and they also improve our body's immune response.*

If you've ever had a flu shot, then you've had a bivalent (or multivalent) vaccine before! Immunologist Tania Watts explains that bivalent vaccines have been a long-established method to keep up with another frequently-evolving virus: the flu.*

She elaborates, "With [the] flu, we do three or four different variants [in one flu shot]. It's just a mixture, and the RNA vaccines are very easy to mix and match. In theory, we could have 10 [variants targeted in one dose]."*

What's the point of having the vaccine for the original version of COVID-19 in the bivalent vaccine?

Dr. Volker Gerdts, who is the director and CEO of the Vaccine and Infectious Disease Organization, says that the best way to protect ourselves from COVID-19 and its variants is to get a vaccine with the broadest protection possible.*

"The whole goal is to have multiple different types in your vaccine to provide broad protection... If we have in this vaccine representation from very different strains, or different variants, then we can assume that we get broad protection also then against future variants," he shares.*

In an email, Moderna Canada's medical director Shehzad Iqbal told CTV News that "bivalent boosters may provide broad protection against several different variants, even ones they weren't specifically designed to fight against."*

When will bivalent boosters be available?

Health Canada still needs to review and approve both of these bivalent boosters for safety and effectiveness. Moderna and Pfizer-BioNTech have both recently submitted their applications for their bivalent boosters to Health Canada for review. Moderna submitted their application on June 30, 2022*, and Pfizer-BioNTech submitted theirs this past Monday, July 25, 2022.*

Assuming that both boosters will be approved, the Omicron-specific Moderna booster will likely be made available sooner than the Omicron-specific Pfizer-BioNTech booster since Moderna's application was submitted almost one month earlier.

In late June, Canada's chief health officer Dr. Theresa Tam confirmed that the timeline for when these bivalent boosters will be available depends on how quickly these review and approval steps are completed.*

An exact timeline can't be confirmed, but Moderna Canada is hoping for their bivalent booster to be available in early fall 2022.* Ontario's chief medical officer of health Dr. Kieran Moore stated that the bivalent boosters might not be available until November or December of this year.*

What are Moderna and Pfizer-BioNTech saying about their bivalent boosters?

Both Moderna Canada and Pfizer Canada say that their bivalent boosters can be updated to address new variants if needed.* This is very positive news because "the virus has continued to evolve since [both companies] began work on their Omicron-adapted vaccines."*

Moderna

Moderna claims that their bivalent booster "prompted higher antibody response against the Omicron variant than the current version of the company's [booster]."*

The company also claims that their bivalent booster showed superior protection "against Beta, Delta and Omicron variants of concern one month after administration, with continued superiority that was durable against Beta and Omicron variants of concern six months after administration." Moderna anticipates that the level of antibodies its newest booster provides "will be more durable over time against Omicron as compared to [its current booster]."

The CEO of Moderna Stephane Bancel stated that: "our bivalent platform continues to demonstrate better performance than the current booster... against all tested variants, including the BA.4/5 and BA.1 Omicron sub-variants. This superior breadth and durability of immune response following a bivalent booster has now been shown in multiple Phase 2/3 studies involving thousands of participants."*

Additionally, Moderna mentioned that their bivalent booster has "the same safety profile as its original Health Canada-approved Moderna COVID-19 vaccine, only that it is updated with the new variant" in a study that examined 437 participants. **,* Moderna stated "there were no vaccine-related serious adverse events."*

It's important to note that Moderna's findings "have not been formally published or peer reviewed." This is why Health Canada has to review and approve bivalent boosters before they are purchased and distributed throughout Canada.

Pfizer-BioNTech

Pfizer-BioNTech also measured how well their booster protects against Omicron.* Early studies demonstrate that their bivalent booster does protect against Omicron, but it provides more protection from Omicron BA.1 than the BA.4 and BA.5 sub-variants.*

The company ran a study with 1,234 participants that were 56 years of age and older.* Participants were divided into two groups: one group got a bivalent booster with 30

micrograms of the new formula and the other group got a bivalent booster with 60 micrograms of the new formula.* The trial found that participants in both groups had safety and side effects results that were similar to the original Pfizer-BioNTech COVID-19 vaccine.*

The CEO and co-founder of BioNTech Dr. Ugur Sahin stated: "The data show the ability of our monovalent and bivalent Omicron-adapted vaccine candidates to significantly improve variant-specific antibody neutralization responses. Omicron has newly evolving sublineages that have outcompeted BA.1 and exhibit a trend of increasing potential for immune escape. We will therefore remain vigilant and are prepared to rapidly adapt our Omicron-adapted vaccine candidates to emerging sublineages if epidemiological and laboratory data suggest."*

In other words, both Pfizer-BioNTech's currently-available, monovalent booster and the new, bivalent booster both increase immune responses against Omicron. He acknowledges that Omicron's sub-variants are more resistant to the bivalent booster than BA.1, but reassures that they are prepared to change the vaccine to protect against future sub-variants if needed.

Final Thoughts

Updating the formula of booster doses to be effective against variants and sub-variants is both safe and necessary to get the broadest protection against COVID-19 as possible. If you have any questions about bivalent boosters, please click here to submit them, and we will answer them anonymously.

Right now, the National Advisory Committee on Immunization (NACI) hasn't released any recommendations about who should get bivalent boosters. This is because NACI only makes recommendations about vaccines that Health Canada has already approved.

When these boosters are approved and NACI makes its recommendations, we will keep you updated about what it says! If you don't know what the NACI is, or if you are curious about their recent recommendations for the fall booster rollout, click here to learn more.

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:

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