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OPINIONCOMMENTARY

CDC Oversells the 'Bivalent' Covid Shot

The FDA approved it without clinical trials, and there's reason to doubt it beats the original vaccine.

. Offit

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The Centers for Disease Control and Prevention recommends that everyone over 12 receive a "bivalent" Covid-19 vaccine as a booster dose. But only a select group are likely to benefit, and the evidence to date doesn't support the view that a bivalent vaccine containing omicron or its subvariants is better than the monovalent vaccine. The CDC risks eroding the public's trust by overselling the new shot.

The existing Pfizer and Moderna mRNA vaccines were designed to protect against the original strain of the novel coronavirus, known as Wuhan-1. The strain that left China, however, was D614G, the first variant. Between January 2020 and December 2021, D614G was replaced by the alpha variant then the delta variant. At the end of 2021, Oxford conducted a study to determine whether the mRNA vaccines still provided protection against severe illness and death caused by the variants. They did.

Then things changed. At the end of 2021, the omicron variant (BA.1) and its subvariants (BA.2, BA.3, BA.4 and BA.5) supplanted delta. Not only was omicron more contagious than delta; it

also evaded immunity. Even the fully vaccinated were at risk of mild illness, and some of severe illness. A third dose was recommended, then a fourth. The CDC found that both a third and fourth dose reduced hospitalizations.

But not everyone benefited. Those who did fell into three groups: the elderly, people with serious health problems and people who were immunocompromised. As the CDC launches its fall booster dose campaign, it would be wise to focus on those at risk rather than the young and healthy.

The new bivalent vaccine contains mRNA from the ancestral strain and BA.4 and BA.5, the subvariants that account for virtually all currently circulating SARS-CoV-2. How does it compare with the old monovalent one? We don't know for sure, because the Food and Drug Administration authorized the new shot without clinical trials. (As a member of the FDA Vaccine Advisory Committee, I voted against the authorization.) But in June Pfizer and Moderna presented data on bivalent vaccines containing the ancestral strain plus BA.1. Those shots were properly studied, and the results were underwhelming.

Participants who had received three doses of the original vaccine were given a fourth dose of the original vaccine or the bivalent one. The virus-neutralizing antibody responses against BA.1 were greater following the bivalent vaccine, but not at a level that was likely to be clinically significant.

Booster doses for Moderna's vaccine contained half an adult dose each of the ancestral vaccine and BA.1. Moderna will be giving two vaccines at booster doses typically given to children. So will Pfizer.

Most worrisome, Moderna recently published a study on the clinical efficacy of the bivalent vaccine containing BA.1. Sixteen cases of SARS-CoV-2 infections occurred: 11 in the bivalent group and five in the monovalent group. For those who suffered clinical illness, five were in the bivalent group and one in the monovalent group. In other words, although the numbers were small, the monovalent vaccine performed *better* than the bivalent vaccine.

Heading into the fall, it would make sense to boost those at greatest risk of hospitalization with Covid-19. We should be careful, however, about overselling the bivalent vaccine as something better than the existing vaccine until more data are available.

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