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Editorial

SARS-CoV-2 (COVID-19) Variants and Vaccine Efficacy

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Classifications and definitions of SARS-CoV-2 (COVID-19) variants

Due to the recent emergence of variants of SARS-CoV-2 (COVID-19), this powerfully contributes to the adapting scientific response to remain effective against the very naturally mutated viruses [1]. The United States Center for Disease Control and Prevention (US CDC) classifies the SARS-CoV-2 (COVID-19) variants as the following [2]:

1) **Variant of interest:** These variants are currently interesting in the United States. These variants are 1.1) B.1.526 (First detected in New York, November 2020, with potential reduction in neutralization by monoclonal antibody treatments and potential reduction in neutralization by convalescent and post-vaccination sera), 1.2) B.1.525 (First detected in New York, December 2020, with potential reduction in neutralization by monoclonal antibody treatments and potential reduction in neutralization by convalescent and post-vaccination sera), and 1.3) P.2 (First detected in Brazil, April 2020, with potential reduction in neutralization by monoclonal antibody treatments and potential reduction in neutralization by convalescent and post-vaccination sera).

2) **Variants of concern**: These variants are 2.1) B.1.1.7 (First detected in the United Kingdom, with approximately 50% increased transmissibility, likely increased severity based on hospital admissions and case fatality rates, minimal impact on neutralization by Emergency Use Authorization (EUA) monoclonal antibody treatments, and minimal impact on neutralization by convalescent and post-vaccination sera), 2.2) P.1 (First detected in Japan or Brazil, with moderate impact on neutralization by EUA monoclonal antibody treatments, and reduced neutralization by convalescent and post-vaccination sera), 2.3) B.1.351 (First detected in South Africa, with approximately 50% increased transmissibility, moderate impact on neutralization by EUA monoclonal antibody treatments, and moderate reduction on neutralization by convalescent and post-vaccination sera), 2.4) B.1.427 (First detected in California, with approximately 20% increased transmissibility, significant impact on neutralization by some, but not all, EUA treatments, and moderate reduction in neutralization using convalescent and post-vaccination sera) and 2.5) B.1.429 (First detected in California, with approximately 20% increased transmissibility, significant impact on neutralization by some, but not all, EUA treatments, and moderate reduction in neutralization using convalescent and post-vaccination sera).

3) **Variant of high consequence:** This variant has clear evidence that medical countermeasures (MCMS) or prevention measures have significant decreased effectiveness that are associated with previously circulating variants. The possible attributes that can impact on MCMS are demonstrated failure of diagnostics, evidence to indicate a significant reduction in vaccine effectiveness, a disproportionately high number of vaccine breakthrough cases, very low vaccine-induced protection against severe disease, significant decreased susceptibility to multiple EUA or approved treatments, and more severe

clinical disease and increased hospital admissions. This variant would require public health officials announce a Public Health Emergency of International Concern (PHEIC).

Vaccine efficacy on SARS-CoV-2 (COVID-19) variants

Recently, in early March 2021, a study demonstrated the efficacy of various COVID-19 vaccines produced by many manufactures in symptomatic SARS-CoV-2 (COVID-19) patients and patients infected with SARS-CoV-2 (COVID-19) variants as the following manufactures (vaccine name), used technology, doses, efficacy against symptomatic disease, and efficacy against variants (B.1.1.7 (first detected in the United Kingdom) and B.1.351 (first detected in South Africa)): 1) Pfizer and BioNTech (Comirnaty), mRNA, 2 doses, 95%, unknown and unknown; 2) Oxford and AstraZeneca (AZD1222), viral vector, 2 doses, 82.4% (12 weeks between doses), 74.6%, to be confirmed (unconfirmed reports as low as 10%); 3) Moderna and the National Institute of Health (NIH) (mRNA-1273), mRNA, 2 doses, 94.5%, unknown (but reports of reduction in neutralizing antibodies), unknown; 4) Gamaleya (Sputnik V), viral vector, 2 doses, 91.6%, unknown, unknown; 5) CanSinoBio (Convidecia), viral vector, 1 dose, 65.7%, unknown, unknown; 6) Novavax (NVX-CoV2373), protein, 2 doses, 95.6%, 85.6%, 60%; 7) John & Johnson (Ad26.COV2.S), viral vector, 1 dose, 72%, unknown, 57%; 7) Sinopharm (BBIBP-CorV), inactivated virus, 2 doses, 79.34%, unknown, unknown (but reports of weekend effect); 8) Sinovac (CoronaVac), inactivated virus, 2 doses, 50.4%, unknown, unknown; and 8) Bharat Biotech (Covaxin), inactivated virus, 2 doses, unknown, unknown, unknown; respectively [3].

The serious adverse events from AZD1222 occurred in 168 patients, 79 in the vaccine group and 89 in the control group [3]. Two cases demonstrated transverse myelitis that later determined to be unlikely to be associated [3], whereas, there is unknown serious adverse events from CoronaVac in phase III trials [3]. More serious adverse events were reported in the control group than in the vaccine group [3]. Recently, the World Health Organization (WHO) stated that in the context without SARS-CoV-2 (COVID-19) variants, particularly B.1.351, the Oxford/AstraZeneca vaccine offers protection against severe COVID-19, COVID-19-related hospitalization and COVID-19-related death [1]. Interesting, the difference of vaccine efficacy of Ad26COV2.S COVID-19 vaccine were demonstrated in the United States and South Africa (72% vs 57%) [4]. The South Africa trials demonstrated lower vaccine efficacy compared with trials in other countries where B.1.351 variant was not dominant [5], whereas a recent study demonstrated that a two-dose regimen of the ChAdOx1 nCoV vaccine did not protect against mild-to-moderate B.1.351 COVID-19 variant [6]. Current COVID-19 vaccines are based on the SARS-CoV-2 spike protein, whereas the SARS-CoV-2 (COVID-19) variants contain mutations in the spike protein that contributes to spurring vaccine efficacy concerns [5].

The WHO recommends on the effectiveness of COVID-19 vaccines in the context of SARS-CoV-2 (COVID-19) variants that: 1) The manufacturers must be prepared to adjust to the SARS-CoV-2 (COVID-19) viral evolution, 2) Trials must be designed and maintained to allow any changes in efficacy to be assessed, 3) Enhanced genomic surveillance must be backed by rapid haring of genetic and meta-data to allow for global coordination and response, 4) Priority should be given to vaccinating high-risk groups everywhere, 5) Governments and donors, as well as development banks, should further support COVAX, and 6) The existing mechanism for tracking and evaluating COVID-19 variants that may affect vaccine composition must be enhanced [1].

The WHO recommendations on COVID-19 vaccines in the context of SARS-CoV-2 (COVID-19) variants contribute to the plans of the next steps on COVID-19 vaccine production, such as Pfizer and BioNTech announced on February 25, 2021 that they had started evaluating the safety and immunogenicity of a third dose of their vaccine to observe whether it would boost immunity to SARS-CoV-2 (C) OVID-19) variants, particularly B.1.351; Moderna announced on February 24, 2021 that it had shipped a booster vaccine candidate based on B.1.351 to NIAID for a phase 1 trial; and Novavax, whose first-generation vaccine has not been authorized yet in the United States, announced on January 28, 2021 that it was working on developing a booster, a combination bivalent vaccine, or both to protect against SARS-CoV-2 (COVID-19) variants [5].

In conclusion, more challenging will be deciding when and how to deploy COVID-19 vaccines 2.0. Modifying COVID-19 vaccines would probably be the most straightforward step in involving SARS-CoV-2 (COVID-19) variants.

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