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Opinion

Planning Ahead for a Possibility of Future Identification of a SARS-CoV-2 Variant of High Consequence

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Abstract

The authors suggest to broaden preparedness for the possibility of emergence of a SARS-CoV-2 variant of high consequence, although such variant has not been identified so far, by planning ahead for a situation where unscheduled development and administration of a modified vaccine will be necessary. They identify and discuss various less-addressed issues whose durations can be shortened by such planning ahead. Some of the issues should be decided and handled on a country-by-country basis. These issues are: what the threshold values of parameters used to determine a variant's rise to the level of high consequence should be; when development of a modified vaccine should actually be initiated; conditions, with respect to each country, that have to be fulfilled in order to determine that an instant, unscheduled vaccination program is necessary; and, with respect to each country, if the necessity of an unscheduled vaccination program is indeed determined, when to actually start such unscheduled vaccination program.

Keywords: COVID-19; SARS-CoV-2; Variant of high consequence; Vaccine

Introduction

The variant B.1.1.7 of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) that was identified in the United Kingdom (UK) in late 2020 (also known as the "UK variant" and by several other names) became dominant in various regions of England from low levels within one to two months [1]. In Israel the first cases attributed to this variant were reported in December 2020 [2], and within less than two months 90% of the coronavirus disease 2019 (COVID-19) detected cases in Israel were attributed to this variant [3]. Another variant, which is known as the "Brazilian variant" (and as "P.1") showed 1.4 - 2.2 times higher transmissibility than in other COVID-19 cases [4].

Although these two variants are just examples of a Variant of Concern (VOC), and the spreading periods mentioned above refer only to some countries, it is reasonable to assume that variants of high consequence may spread at similar or even higher rates. At present, no variants of high consequence, as classified by the Centers for Disease Control and Prevention (CDC), have been identified [5], but if a Variant of High Consequence (VOHC) will ever emerge, a response to emergence of such VOHC is likely to require development of a modified vaccine and unscheduled administration of the modified vaccine, and possibly also development and use of new diagnostics. In view of the short time periods within which such VOHC is likely to spread, it is important to have plans that minimize the time spent at every level of the response to such VOHC outbreak.

Discussion

Our goal is to promote discussion and development of models and tools to assist decision-makers and health authorities and organizations in making decisions in a timely manner in case of emergence of a VOHC, particularly when the response involves or requires unscheduled development and administration of a modified vaccine. We use the term "unscheduled" to refer to a need for administration of a modified vaccine before anticipated third dose scheduling [6] or in interim periods in the following years.

In planning for response to a VOHC outbreak we need to take into account that development including testing and manufacturing of a modified vaccine is likely to take months [7]. Additionally, administration of the modified vaccine may also take months, if not more. For example, one of the fastest vaccination programs was implemented in Israel, and within about 3 months, more than 50% of the population were vaccinated [8]. The periods of time for development, testing, manufacturing and administration of the modified vaccine cannot probably be shortened much, but other, seemingly less-addressed issues probably can. We therefore suggest that decision-makers and health authorities and organizations should be aware of and consider these less-addressed issues, which we point out as follows:

- What the threshold values of parameters used to determine a variant's rise to the level of high consequence should be (e.g., a vaccine effectiveness threshold value below which the vaccine should be considered ineffective, a percentage threshold value of severe clinical disease cases out of total detected cases, and a percentage threshold value of hospitalization cases out of total detected cases).

- When development of a modified vaccine should actually be initiated (e.g., immediately after VOHC declaration even if only a small number of cases have been identified, upon detection of a predefined number of cases or a predefined percentage of cases of total detected cases, upon detection of cases in more than one country, or waiting a predefined period of time to see if the VOHC becomes extinct).

- Conditions, with respect to each country, that have to be fulfilled in order to determine that an instant, unscheduled

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vaccination program is necessary (e.g., based on a number of locally detected cases, according to a recommendation from the World Health Organization (WHO), the time left till the next scheduled vaccination for different population groups, or in response to cases detected in other countries).

- With respect to each country, if the necessity of an unscheduled vaccination program is indeed determined, when to actually start such unscheduled vaccination program (e.g., waiting until a predefined number of cases is detected locally, or as an act of prevention in advance). A correlated issue is whether logistics considerations, such as distribution, in each country will enable initiation of the unscheduled vaccination program.

In respect of issue (b), we note that although vaccine manufacturers have already initiated studies to cope with current variants of concern [7], a timely centrally-coordinated effort may be required or preferred in case of VOHC emergence.

We can therefore assume, based on the examples mentioned above, that in case of a VOHC outbreak, the VOHC will cause the vast majority of cases in 2 months, whereas the response, in the best-case scenario, will lag behind by at least 4 months (taking, for example, 3 months for development, testing, and manufacturing of the modified vaccine + 3 months for administration of the modified vaccine), not taking into account the amount of time needed for dealing with the above-mentioned less-addressed issues. Therefore, it will be of utmost importance to reduce the amount of time spent on the above-mentioned less-addressed issues as much as possible. This may be achieved by investigating and considering these issues and at least partially resolving them before the VOHC outbreak.

We assume that other less-addressed issues for which preplanning may result in reduction of outbreak response time may also exist, and we believe that identification of such issues and preplanning associated thereto would be of considerable value.

Conclusions

Although no variants of high consequence have yet been identified we suggest that, for the purpose of future preparedness and in addition to development and manufacturing of modified vaccines, planning ahead should be conducted on various less-addressed issues related to the possible emergence of a VOHC. Planning regarding these less-addressed issues may assist decision-makers and health authorities and organizations in making decisions quicklier and with more confidence than in the absence of such planning.

The issues we believe to be less-addressed are as follows: what the threshold values of parameters used to determine a variant's rise to the level of high consequence should be; when development of a modified vaccine should actually be initiated; conditions, with respect to each country, that have to be fulfilled in order to determine that an instant, unscheduled vaccination program is necessary; and, with respect to each country, if the necessity of an unscheduled vaccination program is indeed determined, when to actually start such unscheduled vaccination program. We believe that other less-addressed issues for which planning ahead may be beneficial also exist.

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