Developing a framework for evaluating new COVID-19 vaccines
Objectives of the meeting

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Background

More vaccines are needed

Placebo-controlled trials are becoming more difficult

Previous international discussions suggest increasing interest in using immunobridging to make new vaccines available, with some regulators already having committed to such approaches

These discussions also have suggested that there may be concerns with this approach in some cases
Previous discussions

Indicate that neutralizing antibodies when measured shortly after vaccination are reasonably good predictors of vaccine effectiveness against symptomatic disease.

Neutralizing antibodies at later times are not good predictors of waning efficacy over time.

Partly because vaccine protection against severe disease tends to exceed that against mild disease, neutralizing titers that predict high protection against symptomatic disease also predict high protection against severe disease.

Otherwise, although it appears that cell mediated responses can protect against severe disease, we don’t have a reliable method of predicting how well a vaccine will protect against severe disease, especially with new variants.

New variants, especially omicron, are much better at evading humoral than cellular immunity.

Thus, neutralizing antibody titers are likely to be most useful when they also predict other aspects of the immune response.
Principles

Decisions should be science-based

Initially, it will be prudent to focus on areas where consensus may be emerging. This may involve starting with more stringent criteria.

While neutralizing titers may be useful predictors of protection, there is less risk when new vaccines achieve titers corresponding to the most protective vaccines.

Our primary goal is to prevent severe illness and death (long COVID appears to be less common in vaccinated people and those with less severe infections)

We hope to move towards a framework that WHO can use to determine whether or not to issue EULs for new vaccines.

Recognizing that EULs also require support from regulators, WHO also hopes to facilitate discussion among the scientific community that will support science-based decision-making
Today’s discussions

Vaccine attributes that could facilitate decision-making based on immune markers
Where they could be used, how to think about setting criteria for immune markers
Consider additional information that could support use of immune response data in decision-making for new vaccines
How to evaluate vaccines where use of immune markers might not be broadly accepted

How can we arrive at a science-based framework that will facilitate the availability of new effective vaccines?
Recognizing that discussion of criteria for decision-making will be enhanced if there is a concrete proposal to discuss, we will present a possible framework for evaluating new vaccines