Updated evidence and considerations regarding variant-specific vaccines and administration of additional dose

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Session 2. Updated evidence and considerations regarding variant-specific vaccines and administration of additional doses

Panel discussion (15:45 - 16:16):
- How can the available evidence be applied to evaluation of vaccine effectiveness against new variants?
- Remaining knowledge gaps and research priorities
- How can we accelerate getting the needed information?
- What work needs to proceed at risk?
It has been found that there is a high correlation between neutralizing antibody titers by COVID-19 vaccination and the prevention of infection with COVID-19, although ICP has not yet been established.

Immunogenicity data including neutralizing antibody against delta variant combined with observational effectiveness study data in real-world facilitated regulatory decision making on needs and timing of original vaccines booster, although current vaccines are not optimized for delta variant.

This approach is thought to be applicable to Omicron variant.
Omicron variant has both the mutation of the beta variant, which greatly reduces the neutralization antibody titer, and the mutation of the delta variant, which increases SARS-CoV-2 transmission.

Above all, increase in antibody escape and reinfection rate is one of the biggest potential concerns in Omicron variant.

However how much the neutralizing antibody titer of the current vaccines will be lowered is expected to be confirmed within 2 to 3 weeks through a neutralizing antibody assay using the serum from the COVID-19 vaccinated or infected persons.
If Omicron variant will greatly induce antibody escape, booster vaccination with new variant vaccine is necessary. Several developers are preparing for updating to new vaccine for Omicron variant. Some developers who have been developing vaccines for Beta variant predict that their vaccines are effective against Omicron variant.

To date, there is very limited information on the Omicron variant, but if this variant has significant public health impacts, regulatory flexibility will be needed to allow developers to quickly update vaccines that respond to new VOC.
• Although variant vaccine guidelines established by EMA, FDA and ACCESS provide sufficient points to consider when developers want to shift their own parent vaccine to variant vaccine, additional considerations for accelerating variant vaccine development may need to be provided especially if new variant induces significant breakthrough infection and severe disease in previous vaccinees.

• Additionally, in order to shorten the development period of new variant vaccines by developers, the distribution of Omicron variant and disclosure of genetic information should be quickly followed.