World Health Organization

— MEETING REPORT —

2nd Global Consultation on SARS-CoV-2 Variants of Concern and the Impact on Public Health Interventions

10 June 2021

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Background

As the COVID-19 pandemic has progressed, variants of the virus have emerged, and more are expected as the virus continues to evolve, but not every variant will be of interest or of concern. Noting the urgent needs for shared access to information, coordination and prioritization of research to assess their potential impact, consistent communications, and joint action, WHO has developed an integrated approach to monitoring and assessing SARS-CoV-2 variants of concern (VOCs) and their impact on public health interventions, including public health and social measures, vaccines, diagnostics, and therapeutics.

Noting the upsurge in COVID-19 cases in parts of the world and the emergence of the Delta VOC, there was an urgent need for the global community to come together again to review and synthesize the available evidence of the impact of VOCs on public health interventions. To ensure continued coordination and harmonization for interpreting results, issuing recommendations, and communicating to the public, WHO convened the 2nd Global Consultation on SARS-CoV-2 Variants of Concern and their Impact on Public Health Interventions on 10 June 2021. This meeting report summarizes the available information as of 10 June 2021.

The recording from this consultation can be found *here* (passcode: m#t9b!Tl).

Objectives of the consultation

1. Review and summarize the existing evidence of the impact of VOCs on public health interventions
2. Engage global stakeholders to outline information needs and decision-making processes for assessing the impact of VOCs on public health interventions
3. Outline decision-making processes for COVID-19 vaccine composition, if needed

Opening session

Dr Mike Ryan (WHO) opened the consultation by emphasizing the importance of global coordination against SARS-CoV-2 variants due to the risk of emerging variants that may challenge public health interventions and strategies. Therefore, it is critical that the global community come together to strengthen and leverage existing systems and assets to monitor the variants and their impact on public health interventions.

Dr Sylvie Briand (WHO) provided an update on the current global situation with the SARS-CoV-2 pandemic. The virus continues to evolve, and SARS-CoV-2 VOCs are reported around the world. Since the first global consultation on SARS-CoV-2 variants and their impact on public health interventions on 29 March 2021, a new VOC, the Delta variant that was first detected in India in October 2020, has emerged. WHO is setting up two Technical Advisory Groups (TAGs) to advise on various aspects of the response to variants:

- TAG-VE (virus evolution), which will characterize VOIs and VOCs; and
- TAG-CO-VAC (vaccine composition), which will interpret available evidence and provide recommendations for adapting COVID-19 vaccine composition, if needed.

Session 1:
Focus on SARS-CoV-2 Variants

The first session addressed SARS-CoV-2 variants nomenclature, epidemiology, and viral evolution.

Dr Lorenzo Subissi (WHO) provided an update on the VOI/VOC designation process and naming system. It was emphasized that viral evolution is expected, and most mutations do not result in a change of viral behavior. WHO designates variants that do result change in in viral behavior as variants of interest (VOIs) or VOCs. VOIs have genetic mutations that may lead to changes in virus behavior and cause community transmission or multiple COVID-19 cases/clusters or have been detected in multiple countries; VOCs require closer monitoring as they have global public health significance and may be associated with increased transmissibility, different clinical disease presentation, or reduced effectiveness of public health interventions. The SARS-CoV-2 Virus Evolution Working Group, which is in the process of being formalized as the TAG-VE, was established in June 2020 to detect new mutations and variants quickly, assess their potential public health impact, and identify research gaps. As June 10, 2021, six VOIs and 4 VOCs were being monitored.

To assist with public discussions of variants, a new naming system based on the Greek alphabet was recently developed by the VEWG. The established systems for naming and tracking SARS-CoV-2 lineages, i.e., GISAID, Nextstrain and Pango, will remain in use in the scientific community, and VOIs and VOCs will be linked to their scientific name.

Prof Wendy Barclay (Imperial College London) discussed scientific efforts in assessing the risk of SARS-CoV-2 variants. Analyses show that SARS-CoV-2 evolution follows a pattern expected of zoonotic virus transmission into humans. Shortly after emergence into humans, the virus rapidly mutated to adapt to the new host and confer a fitness advantage. As of 10 June 2021, all four VOCs contained constellations of mutations, rather than single point mutations, suggesting that they are evolving within individuals. As such, continued evolution is expected, and most mutations may be of no consequence. However, some mutations may result in mechanisms that allow for increased disease severity, escape from immune responses, decreased effectiveness of antiviral treatment, or infection in a new animal host.

Current evidence suggests that most of the variants evolve to similar functions, with mutations occurring in similar key locations. Laboratory analysis shows that VOCs have some antigenic distance from vaccine immunogens, and early results from the United Kingdom suggest that vaccine effectiveness is slightly reduced for the Delta variant compared to the Alpha variant but are still above the efficacy threshold assigned in the WHO target product profile. However, vaccines continue to be effective at protecting against severe disease and hospitalization.

Brett Archer (WHO) presented on the global epidemiological situation with SARS-CoV-2 variants. There is widespread detection of VOCs and VOIs in all regions, and analysis of variants over time in countries using the GISAID database shows that some become dominant in most countries, quickly displacing other circulating variants. All VOCs and some VOIs demonstrate increased transmissibility over other circulating variants, with analysis of GISAID data suggesting that the Delta variant may be significantly more transmissible. The evidence for increased risk of hospitalization or death is mixed for all VOCs, and it is difficult to determine if it is due to a change in viral pathogenesis or a result of large-scale transmission putting extreme pressures on health systems and potentially delaying diagnosis and care for patients. Likewise, there is mixed evidence of a potential increased risk of COVID-19 reinfection by some VOCs following recovery from natural infection caused by previously circulating variants; further studies are needed to understand the extent of this. Currently, standard PCR and antigen based rapid diagnostic tests remain largely effective at detecting the current VOCs.

More transmissible variants will take advantage of opportunities to spread, but surges are likely not only the result of an introduction of a new variant. Factors

like the relaxation of public health and social measures and a susceptible population due to low vaccination coverage and heterologous seroprevalence likely allow more transmissible variants to emerge and spread. When surges do occur, proven response strategies (public health and social measures, infection prevention and control in health facilities,) have repeatedly demonstrated their ability to bring transmission levels under control in countries that experience rapid variant replacement by VOCs concomitant to case surges. Therefore, it is important to maintain and reinforce these strategies.

WHO, through the *COVID-19 Weekly Epidemiological Updates*, continues to provide weekly updates on VOCs and VOIs, including fortnightly updates on emerging evidence of phenotypic impacts.

Session 2:
Evidence Framework for Variants & COVID-19 Vaccines

The second session focused on the evidence framework and information needs for assessing VOC and their impact on COVID-19 vaccines.

Dr Philip Krause (WHO R&D Blueprint COVID-19 Vaccines Working Group) discussed the decision-making process and methods to decide if a modified vaccine or a new vaccine is needed. There is a wide array of vaccines in use and in development around the world, with differing platforms and delivery mechanisms. There are also differing antigen needs and proposals for booster doses of modified vaccines across countries.

Any decisions made about vaccine modifications will have repercussions on the global supply with consequences on vaccine access. Because of this, it has been agreed that WHO will coordinate the global response and decision-making process for modifying COVID-19 vaccine composition. These decisions will be informed by diverse data, including from evolutionary biology, animal models, epidemiology of disease (transmissibility of variant, severity of disease, incidence trends), randomized evidence, non-randomized evidence, etc. Time to manufacture and scale-up capacity for different COVID-19 vaccines should also be taken into consideration. The TAG-CO-VAC Expert group will use this information to advise on the composition for modified COVID-19 vaccines, if needed.

Ideally, new vaccines would protect against all circulating variants, especially those that first generation vaccines may be less protective against. The convergence of mutations among VOCs suggests that vaccines could address multiple variants, but careful thought must be given to how specific antigens are selected so that they may provide broad protection. Most of the world is not vaccinated, and variant-specific vaccines for non-immune individuals could be used if they confer broader protection than prototype vaccines. Previously vaccinated individuals may already have substantial protection against many variants, so boosting would be for the purpose of immunity against new variants. Preferably, a modified vaccine would protect both non-immune and immune individuals against diverse antigens, circulating and anticipated.

Timing of booster vaccinations remains unclear while current vaccines are still effective. Avoiding unnecessary vaccination is preferred; however, preventable harm may occur if boosters are deployed only when vaccines lose efficacy. Ideally, booster strategies would retain efficacy against original strains, while also covering new variants that could evade vaccine immunity. Having tested variant vaccines before they are needed would facilitate rapid deployment of broadly protective boosters.

Prof Isabelle Boutron (Cochrane France, Université de Paris) discussed efforts to review and critically appraise randomized evidence on vaccines and variants. Randomized evidence is important for assessing the effectiveness and safety of COVID-19 vaccines. Cochrane France, in collaboration with several international teams, is conducting a living systematic review of randomized control trials (RCTs) with any COVID-19 vaccine as an intervention and the following as primary outcomes: confirmed SARS-CoV-2 infection, confirmed symptomatic COVID-19 after complete vaccination, severe or critical COVID-19, all-cause mortality, systemic adverse events, and any and serious adverse events. All results are available at covid-nma.com. Variant data from these trials are being extracted for analysis.

Out of 43,000 citations screened, 39 RCTs were identified, and five had variant data. Most (n=4) were a post-hoc analysis of variants with sequencing done on cases to

which they had access, resulting in a lack of statistical power for assessing vaccine efficacy of vaccines against variants. Because they are post-hoc analyses, there are missing outcome data, namely sequencing data, which could bias the analysis results. However, even when the vaccine efficacy is reduced, the studies show that it remains above the 50% threshold.

Prof Julian Higgins (University of Bristol) discussed the review and critical appraisal of non-randomized evidence on vaccines and variants. While not a substitution for RCTs, observational studies can provide useful supplemental information on SARS-CoV-2 variants and COVID-19 vaccines, such as data from population subgroups not enrolled in RCTs, long-term or less-common outcomes (e.g., death), differences between real-world implementation and clinical trial context, and emerging evidence for SARS-COV-2 variants. These studies can provide abundant information; a literature search for observational studies on SARS-COV-2 variants and vaccine effectiveness identified 37 studies meeting these criteria with varying study design and peer-review status.

Evidence from observational studies must not be overlooked as this will likely be the first data available. However, observational studies often contain significant biases, including due to confounders, participant selection, and missing data. Age, time, COVID-19 symptoms, and health-seeking behaviors are examples of confounders that individually affect the variables of vaccination status and infection outcome. Confounders can be adjusted and considered in the analysis, but even when adjusting for obvious confounders, residual confounders often remain. A test-negative case-control study is a useful study design for COVID-19, which controls for people who decide to get a SARS-COV-2 test. However, even with this study design, additional confounders may remain and the impact of selection bias (restricting to individuals with test results) in this study design is not well understood yet. Because of these issues, observational studies on COVID-19 and variants will need to be examined carefully to identify potential biases in their results.

Eleven vaccine developers (see Annex 1 and 2 for the list of developers and speakers) presented on current efforts to design and test vaccines across different platforms that are protective against variants. A few developers have begun efficacy testing (Pfizer, AstraZeneca, Janssen), while most others have preclinical or early clinical studies showing immunogenicity against VOCs. Some developers are already developing or are planning to develop variant-specific vaccines.

The second session ended with a panel discussion of preliminary considerations of other epidemiological data to inform decisions featuring **Prof John Peter Figueroa (University of the West Indies)**, **Dr Mary Ramsay (Public Health England)**, **Prof Helen Rees (University of Witwatersrand)**, and **Dr David Wentworth (US CDC)**. Panellists repeatedly highlighted the needs for detailed and integrated epidemiological and genomic surveillance data, especially from low- and middle-income countries, and monitoring features such as transmissibility, virulence, and disease presentation. Panellists also cited the need for systematic tracking of breakthrough infections in previously infected or vaccinated individuals. Breakthrough infections among clusters or a surge of cases may be a signal for the emergence of new variants, and they also allow for investigation of immunity duration. Additional phenotypic data to understand antigenic changes and escape from prior infection or vaccination is also needed to stay on pace with the rapidly evolving SARS-CoV-2 virus.

Session 3:
Impact on Public Health Decision-Making

The third session explored information needs and other considerations for public-health decision making on SARS-CoV-2 and variants.

A panel of vaccine developers and regulators, including **Dr Chang-Joon Bae (Ministry of Food and Drug Administration, Republic of Korea)**, **Dr Marco Cavaleri (EMA)**, **Dr Adam Hacker (CEPI)**, and **Dr Philip Krause (US FDA)**, provided their perspectives on variants and COVID-19 vaccines. It was iterated that more data on the immunogenicity and duration of immunity induced by current vaccines is required before deciding on booster vaccines. Evidence is limited as duration of immunity studies are still in progress, but what is available so far suggests that neutralizing and binding antibodies are maintained at least 5-7 months after vaccination and memory T cells are present 8 months after the last immunization. Current vaccines also appear to be protective against mild and moderate COVID-19. Another consideration is how implementation of a booster dose could be used to increase global access to vaccines versus affecting supply negatively and leading to widened gaps in vaccine equity.

Heterologous vaccine boosting strategies using first generation and variant-specific vaccines could be considered in addition to vaccines in development, such as multivalent vaccines. Because of the wide diversity of vaccines in the pipeline, evaluating the efficacy of combination boosting strategies will be complicated and not feasible through RCTs in the timeframe that these vaccines may become necessary to deploy. Therefore, decisions will need to rely on immunobridging and immune correlates of protection. Supporting the research and development pipeline and fostering innovation are critical to responding as quickly as possible to a change in vaccine efficacy because of variants. To this regard, the regulatory community must provide guidance now to developers on what they will expect from new vaccines.

Regulators agreed there is a need for ongoing work to assess whether to boost current vaccines. If/when that becomes necessary, it will be important that whatever is used (i.e., a third dose of prototype vaccines or a variant-specific vaccine) induces broad protection in both immunized and naïve individuals. It was emphasized that vaccine effectiveness with circulating variants data, especially for vaccines for which there is little data available, are needed to determine if and when a modified vaccine or booster is needed.

Additionally, there must be consensus on the level of protection against mild, moderate, or severe disease that is desired and being evaluated. A booster may not be necessary if reduced efficacy against mild disease occurs, but current vaccines protect against severe disease.

Given the differential prevalence of variants, vaccine availability, and vaccination rates, implementation of a mix and match approach may be considered so long as highly immunogenic vaccines are used where possible. Comparative studies should ideally be done within the same platform with similar immunogenicity profiles. However, in situations where this is not possible, more consistent guidance from regulatory agencies on immunobridging between different vaccine technologies is necessary and may require innovative study designs.

Dr Christine Carrington (University of the West Indies), **Dr Nazeem Muhajarine (CoVaRR-Net)**, and **Dr Hanna Nohynek (SAGE)** offered country and global-level perspectives on the impact of variants on public health decision-making. The call for better integration of genomic, phenotypic, and epidemiological surveillance was echoed, including at the sub-national level. There is a need to incorporate clinical and demographic data into phylogenetic analyses to better characterize outbreaks and more effectively inform public health

policy. A significant barrier to obtaining this is the human resources to carry it out. For example, genomic surveillance in the Caribbean region was initiated as part of a research project, and while it now receives support from PAHO, it is not enough to carry out routine surveillance at the scale or speed required.

Information on the impact of SARS-CoV-2 variants on vaccines is very limited at this stage. Immunological data is abundant, but it is unclear how predictive of clinical efficacy it may be. Furthermore, criteria for clinical efficacy vary across trials and strain characterization is often missing, making these scarce data difficult to interpret. More complete evidence on variants and their impact on public health interventions is required for evidence-based recommendations, which could be informed by modelling-based analyses.

Viral and human behavioral dynamics will change seasonally and may influence variant emergence in different regions of the world, emphasizing the need for a globally coordinated response to controlling variants. An integrated early-warning system would be a useful tool for governments and public health systems planning and preparation.

Public health decision making, including the resulting decisions and messages, is a balance between acknowledging and taking seriously the threat of variants, increasing vaccination coverage, and moving towards relaxed public health and social measures. Innovative partners have proven to be useful for generating and reviewing evidence and informing public health decision making. Canada has taken an interdisciplinary approach in their response to variants through the Coronavirus Variants Rapid Response Network (CoVaRR-Net). which bridges expertise from more than 40 researchers in biomedical research, social sciences, public health, indigenous engagement, and policy. The network is sharing resources and connecting with local leaders and federal policymakers to contextualize evidence and make it actionable for a rapid and bottom-up public health response to COVID-19.

Conclusions and Next Steps

Dr Jaouad Mahjour (WHO) closed the consultation and provided the final key messages:

- WHO remains committed to coordinating the response against SARS-CoV-2 variants by supporting its Member States and collaborating with stakeholders.
- The public health interventions in place for COVID-19, including public health and social measures, infection prevention and control, and vaccines, are still effective against the current VOCs (Alpha, Beta, Gamma, and Delta variants).
- Variants will continue to emerge over time, and this is expected. While not all will be of concern, continuous monitoring and assessment is necessary. WHO's TAG-VE will continue to advise WHO on the characterization of VOIs and VOCs.
- Because more variants will likely emerge, there is a critical need to continue assessing the available evidence of impacts on therapeutics, diagnostics, and current and future COVID-19 vaccines. WHO is establishing the TAG-CO-VAC to interpret available evidence and provide recommendations for adapting COVID-19 vaccine composition, if needed.

WHO will continue to hold regular consultations to provide an open forum for the sharing of the most up to date evidence regarding SARS-CoV-2 variants and their impact on public health interventions.

Annex 1:
Consultation Agenda

Chair: Sylvie Briand

TIME	TOPIC	SPEAKERS
13:00-13:05	Opening remarks	*Mike Ryan*
13:05-13:10	Updates on the WHO global risk monitoring and assessment framework for SARS-CoV-2 variants	*Sylvie Briand*
SESSION 1: FOCUS ON SARS-COV-2 VARIANTS		
13:10-14:10	Update on VOI/VOC designation process and naming system Global epidemiological situation with SARS-CoV-2 variants Risk assessing SARS-CoV-2 variants *Moderator: Maria Van Kerkhove*	*Lorenzo Subissi* *Brett Archer* *Wendy Barclay*
SESSION 2: EVIDENCE FRAMEWORK FOR VARIANTS & COVID-19 VACCINES		
14:10-15:20	Decision-making process and methods to decide if a modified vaccine or a new vaccine is needed Review and critical appraisal of randomized evidence on vaccines and variants Review and critical appraisal of non-randomized evidence on vaccines and variants Developers' corner – current data and plans for evaluation of the effect of variants on vaccine efficacy/effectiveness Preliminary considerations of other epidemiological data to inform decisions *Moderator: Kanta Subbarao*	*Philip Krause* *Isabelle Boutron* *Julian Higgins* *Luigi Aurisicchio* *Prakash Bhuyan* *J Robert Coleman* *Philip Dormitzer* *Randall Hyer* *Mathieu Le Gars* *Allen Lien* *Krishna Mohan* *Piyush Patel* *Trina Racine* *Christine Roberts* *John Peter Figueroa* *Mary Ramsay* *Helen Rees* *David Wentworth*
SESSION 3: IMPACT ON PUBLIC HEALTH DECISION-MAKING		
15:20-15:50	Perspectives of regulators and developers for variants and COVID-19 vaccines *Moderator: Marco Cavaleri*	*Chang-Joon Bae* *Adam Hacker* *Philip Krause*
15:50-16:25	Impact of variants on public health decision-making: · Global perspective · Country level perspectives *Moderator: Nyka Alexander*	*Christine Carrington* *Nazeem Muhajarine* *Hanna Nohynek*
16:25-16:30	Concluding remarks	*Jaouad Mahjour*

Annex 2:
Speakers and Moderators

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Participants

The virtual consultation was attended by **1,909 participants** from **132 countries, areas, and territories**.

The consultation was organized by WHO Headquarters staff in the Global Infectious Hazards Preparedness Department, in collaboration with staff from the R&D Blueprint; Health Information Management Department; Regulation and Prequalification Department; and the Immunization, Vaccines, and Biologicals Department.

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