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XBB.1.16 Updated Risk Assessment, 05 June 2023

XBB.1.16 was first reported on 09 January 2023, designated as a Variant Under Monitoring (VUM) on 22 March 2023, and designated as a Variant of Interest (VOI) on 17 April 2023.

XBB.1.16 is a descendent lineage of XBB, a recombinant of two BA.2 descendent lineages. XBB.1.16 has a similar genetic profile as XBB.1.5, with the additional E180V and K478R amino acid mutations in the spike protein compared to their parent XBB.1 lineage.

As of 5 June 2023, 19 847 sequences of the Omicron XBB.1.16 variant have been made available from 66 countries. A majority of the XBB.1.16 sequences are from India (40.7%, 8086 sequences). The other countries with at least 100 sequences include the United States of America (10.9%, 2172 sequences), Australia (6.5%, 1291 sequences), China (6.1%, 1214 sequences), Canada (5.6%, 1104 sequences), Singapore (5.6%, 1118 sequences), Japan (4.5%, 890 sequences), South Korea (4.3%, 846 sequences), United Kingdom (3.0%, 595 sequences), Thailand (1.5%, 307 sequences), Malaysia (1.5%, 291 sequences), Sweden (1.3%, 261 sequences), Austria (0.9%, 176 sequences), Indonesia (0.7%, 140 sequences), Brunei (0.6%, 112 sequences) and Vietnam (0.6%, 115 sequences).

Globally, there has been a weekly rise in the prevalence of XBB.1.16. During epidemiological week 20 (15 to 21 May), the global prevalence of XBB.1.16 was 16.8%, an increase from 4 weeks prior (epidemiological week 16, 17 to 23 April 2023), when the global prevalence was 10.2%.

The global risk assessment for XBB.1.16 is comparable to the other currently co-circulating XBB variants with available evidence (see risk assessment table below). While growth advantage and immune escape properties have been observed in different countries and immune backgrounds, no changes in severity have been reported in countries where XBB.1.16 is reported to be circulating.

Taken together, available information does not suggest that XBB.1.16 has additional public health risk relative to the other currently co-circulating Omicron descendent lineages. However, XBB.1.16 may continue to dominate in some countries and cause a rise in case incidence due to its growth advantage and immune escape characteristics.

The WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) continues to regularly assess the impact of variants on the performance of COVID-19 vaccines to inform decisions on updates to vaccine composition (1).

The risk assessment below is based on currently available evidence and will be revised regularly as more evidence and data from additional countries become available.

Overall risk assessment: Low	Based on its genetic features, immune escape characteristics and growth rate estimates, XBB.1.16 may continue to spread globally and drive an increase in case incidence. XBB.1.16 has spread to 56 countries. From reports by India and Singapore, no increases in COVID-19 disease severity have been observed. Taken together, available evidence does not suggest that XBB.1.16 has additional public health risks relative to the other currently co-circulating Omicron descendent lineages.		
Indicator	Evidence	Level of Risk	Level of Confidence
Growth advantage	Comparing the month of March and the month of April 2023 in India, the proportion of XBB.1.16 relative to other circulating variants rose from 70.3% (3260/4638) to 81.9% (3373/4121). Similarly, for countries with more than 100 sequences, the prevalence of XBB.1.16 rose from 1.1% (425/40 459) to 5.4% (1036/19 223) for the United States of America (USA), 4.1% (177/4329) to 12.6% (527/4221) for Australia, and 0.8% (91/11015) to 5.4% (435/8093) for Canada. From WHO's internal variant growth rate analysis, similarly used by the UK Health Security Agency (UKHSA), XBB.1.16 is among the fastest growing circulating variants globally, and regionally in PAHO, EURO, SEARO and WPRO (2). US Centers for Disease Control and Prevention (CDC) Nowcast model-based projections predict a rise of the XBB.1.16 variant to 14.3% (95% predictive interval 11.1-18.1%) by 13 May 2023 (3). * see footnote for more explanations	Moderate	Moderate
Antibody escape	Similar to XBB.1 and XBB.1.5, XBB.1.16 neutralization assays have demonstrated resistance to BA.2 and BA.5 breakthrough infection sera (4) The sensitivity of XBB.1.16 to convalescent sera of XBB.1-infected hamsters was comparable to those of XBB.1 and XBB.1.5, which points at a similar ability of these variants to evade immunity (4). Additionally, a study showed similar characteristics regarding cell line tropism, host cell entry efficiency and neutralization evasion between XBB.1.16 and XBB.1.5 (9). ** see footnote for more explanations	Moderate	Moderate

Severity and clinical considerations	An analysis of the clinical features of COVID-19 cases from Maharashtra, India, did not report any differences in hospitalization and oxygen requirement for XBB.1.16 as compared to other co-circulating lineages (5). While there was a slight rise in bed occupancy in some states in India (2-4%) as XBB.1.16 emerged and became the dominant variant, these levels were much lower compared to the levels recorded during the Delta wave in early-to-mid 2021 and the Omicron BA.1/BA.2 wave in late 2021 to early 2022 (6). Notably in India, over 70% of the population have received a booster vaccine (7). A recent study investigating the outcomes of hospitalization and severe COVID-19 cases among individuals infected with different XBB subvariants in Singapore observed no significant differences in severity or hospitalization across different XBB subvariants (8). The antiviral sotrovimab exhibits antiviral activity against XBB.1.16, similar to other XBB subvariants (4). *** see footnote for more explanations	Low	Moderate

Annex:

*** Growth advantage**
Level of risk: Moderate, as since the first report of the emergence of XBB.1.16 on 09 January 2023, the variant has not led to a global sweep as some previous variants did. In addition, VUMs such as XBB.1.9.1, XBB.1.9.2 and XBB.2.3 are similarly rapidly growing and it is not clear if XBB.1.16 might sustain the growth advantage to outcompete these variants and become dominant globally.

Confidence: Moderate, as the growth advantage has been estimated by several groups of experts and in several countries and WHO regions.

**** Antibody escape**
Level of risk: Moderate, due to a similar immune evasion profile as XBB.1.5, the current dominant variant globally.

Confidence: Moderate, as immune escape results are based on work from two laboratories. Additional laboratory studies would be needed to further assess the risk of antibody escape.

***** Severity and clinical considerations**
Level of risk: Low, as two countries with a high circulation of XBB.1.16, i.e. India and Singapore, have reported no differences in hospitalization and severe COVID-19 in individuals infected with XBB.1.16 and other co-circulating variants.

Confidence: Moderate, as there is regular coordination and data sharing with all WHO Regional colleagues, countries and partners continue, and as such we continue to receive early signals from countries whenever severity rises.

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References

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