

Evidence check

5 February 2021

Rapid evidence checks are based on a simplified review method and may not be entirely exhaustive, but aim to provide a balanced assessment of what is already known about a specific problem or issue. This brief has not been peer-reviewed and should not be a substitute for individual clinical judgement, nor is it an endorsed position of NSW Health.

SARS-CoV-2 variants

Evidence check question

What is the evidence of the new SARS-CoV-2 variants (501Y.V1, 501Y.V2 and variant P.1) in terms of their infectivity, virulence, and effectiveness of the current vaccines?

Living Evidence - SARS-CoV-2 variants

This document is up to date as of 22 January 2021.

On the ACI website, living evidence tables are reviewed daily and updated as new evidence and information is published. They provide high level summaries of key studies and evidence on a particular topic, and links to sources.

Viruses constantly change through mutation and over time, new variants of a virus are expected occur. Some variants have characteristics that have a significant impact on transmissibility, severity of disease and effectiveness of vaccines. This table includes information on variants that are currently causing concern in the scientific community.

The living evidence table on SARS-CoV-2 variants is [available here](#).

In brief

- Viruses constantly change through mutation and over time new variants of a virus are expected to occur.(1)
- New SARS-CoV-2 variants have recently emerged, most notably in the United Kingdom (UK), known as 501Y.V1, (variant of concern (VOC) 202012/01, or B.1.1.7 lineage) and in South Africa known as 20C/501Y.V2 or B.1.351 lineage and in Brazil known as the P.1 variant.(2, 3)
- Other variants have recently emerged in Nigeria and Japan.(1, 4)
- According to the World Health Organization the vaccines that have been approved should provide protection against variants, as the vaccines elicit a broad immune response.(12)
- While public health measures such as physical distancing, limitations on large gatherings and masks should remain effective, control of a more transmissible variant will require more widespread adoption of these measures.(5)

501Y.V1 variant (United Kingdom)

- The new variant is defined by a set of 23 changes or mutations, one of the most significant is an N501Y mutation.(6)
- Population genetic models of the UK variant have estimated to be up to 71% more transmissible than the previously circulating form of the virus, and it may also have a higher viral load.(5, 7-10) A recent Danish modelling study (January 2021) estimated that the new variant was 36% more transmittable than the other variants.(3)
- Contact tracing and genomic sequencing data in the UK suggests that the secondary attack rate may be higher for cases compared to cases with other variants (15.1% vs 9.8%).(11)
- The new variant appears to be no worse than the previous dominant strain of SARS-CoV-2 in terms of the risk of hospital admission, severity of illness, or mortality.(7) Preliminary analyses also indicate that there is no change in occurrence of reinfection between variant cases compared to other SARS-CoV-2 viruses circulating in the UK.(12)
- While there is no information that infections with these strains are more severe, the impact of COVID-19 disease in terms of hospitalisations and deaths is assessed as high, particularly for those in older age groups or with co-morbidities.(13)

501Y.V2 variant (South Africa)

- The World Health Organization has reported that one of the mutations (N501Y) identified in the UK variant has also been reported in South Africa.(9)
- Preliminary studies suggest the variant is associated with a higher viral load, which may suggest potential for increased transmissibility.(12)
- One mathematical modelling study estimates that 501Y.V2 is 50% more transmissible than pre-existing variants of SARS-CoV-2.(14)
- At this stage, there is no clear evidence of the new variant being associated with more severe disease or worse outcomes.(2, 12, 14)
- One study suggests that the 501Y.V2 lineage of the SARS-CoV-2 is largely resistant to neutralizing antibodies formed by being infected with previously circulating lineages and therefore poses significant re-infection risk. It may also reduce effectiveness of vaccines which are based on immune responses to spike, requiring rapidly adaptable vaccine design platforms.(15)

P.1 variant (Brazil)

- The new variant has 11 amino acid changes to the spike protein, including N501Y(3)
- Information on the epidemiology of this variant is very limited. Currently there is no evidence available to determine a change in transmissibility or disease severity.(3)
- Increase in transmissibility is plausible due to presence of amino acid change N501Y. (3)
- The P.1 lineage was found in 42% of the samples collected from positive cases between 15 to 23 December 2020. Recent rapid increase in SARS_CoV_2 cases in locations with previous very high infection rates may potentially indicate an increased transmissibility or re-infection rates of the new variants, which needs urgent investigation.(16)

New variants and the effectiveness of current vaccines

- The first COVID-19 vaccine approved for emergency use by the World Health Organization is the Pfizer-BioNTech COVID-19 vaccine.(17) Other vaccines currently authorised or approved in various jurisdictions include vaccines by Moderna, Oxford-AstraZeneca, Sinovac, BARDA, Gamaleya Research Institute, Federal Budgetary Research Institution State Research Center of Virology and Biotechnology, Bharat Biotech and two from Sinopharm.(18)
- General consensus from low quality evidence and opinion is that there is no evidence that the UK or South African variants have any impact on vaccine efficacy.(2, 9) Most scientists believe that vaccines currently in development should provide protection against variants, as the vaccines elicit a fairly broad immune response.(19)
- A pre peer review study suggests that the mutations would not result in immune evasion of linear epitopes for a large majority of these COVID-19 patients.(20)
- Pfizer and BioNTech announced results from a pre peer review study on serum samples from 20 participants in a previously reported trial of the mRNA-based COVID-19 vaccine BNT162b2.(21) It found the vaccine protected against the N501Y mutation present in the UK and South African variants.(22)
- Moderna states its vaccine-induced immunity would be protective against the UK variant.(23)
- The Australian Health Protection Principal Committee advises vaccines procured for Australia induce a broad immune response to protect individuals so there is no evidence at this stage that these vaccines would not be effective.(24)
- The vaccine may need to be altered over time as more mutations occur, as happens with the seasonal flu virus.(6)

Limitations

Evidence on the new variants of SARS-CoV-2 is rapidly emerging and low-quality evidence including scientific news articles, studies that have not yet been peer reviewed and modelling studies, have been included in this evidence check.

Background

Many variants of SARS-CoV-2 have been reported throughout the course of the pandemic. A variant analysis was published in November 2020 where results showed variants occurring within the assembled genomes yields 417 variants occurring in at least 1% of the completed genomes. The study found 44 common variants, where 20 result in nonsynonymous mutations.(25)

Over the course of the pandemic, the clinical, scientific, and public health communities have had to respond to new viral genetic variants.(5) New SARS-CoV-2 variants have recently emerged. The scientific community is working toward learning more about these variants, how they might be transmitted, and whether the vaccines will be protective against them. Currently, there is no evidence these variants cause more severe illness or increased risk of death.(2)

Methods (Appendix 1)

PubMed, Google, and MedRxiv were searched on the 11 January 2021. The document was updated on 22 January 2021 using the risk assessment document by the European Centre for Disease Prevention and Control.(3)

Results

Table 1 SARS-CoV-2 new variants

Source	Summary
Peer reviewed sources	
<p>Genetic variants of SARS-CoV-2 — what do they mean?</p> <p>Lauring, et al. January 2021 (5)</p>	<ul style="list-style-type: none"> • Viewpoint. • Lineage B.1.1.7 is a phylogenetic cluster rapidly spreading in south-eastern England. • As of 28 December 2020, this variant accounted for approximately 28% of cases of SARS-CoV-2 infection in England. • Population genetic models suggest that it is spreading 56% more quickly than other lineages. • It has seemingly achieved dominance by outcompeting an existing population of circulating variants, which suggests the virus that is more transmissible at a population level. • Eight of the lineage B.1.1.7 mutations are in the spike glycoprotein, including N501Y in the receptor binding domain, deletion 69_70, and P681H in the furin cleavage site. These mutations could plausibly influence angiotensin-converting enzyme 2 (ACE2) binding and viral replication. • The 501Y spike variants are predicted to have a higher affinity for human ACE2, and a different variant, also with an N501Y mutation, is rapidly spreading in South Africa. • The effects of these mutations on antigenicity are currently unclear.

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Source	Summary
<p>New variant of SARS-CoV-2 in UK causes surge of COVID-19</p> <p>Kirby January 2021 (7)</p>	<ul style="list-style-type: none"> • Commentary. • Despite lockdown and the approval of two vaccines, cases are increasing sharply in parts of the UK due to a new variant of SARS-CoV-2, which various modelling exercises have estimated to be up to 70% more transmissible than the previously circulating form of the virus. • In September 2020, this variant represented just one in four new diagnoses of COVID-19, and by mid-December this had increased to almost two thirds of new cases in London. • The proportion of cases caused by the new variant was different in different regions and so different levels of restrictions were imposed accordingly. Some commentators have questioned the logic of this move. • According to research by the UK Health Agency Public Health England published on 29 December 2020, the new variant appears to be no worse than the previous dominant strain of SARS-CoV-2 in terms of the risk of hospital admission, severity of illness, or mortality. • The new variant has piled additional pressure on to the speed at which vaccination must be achieved. • Driven by the new variant, the UK has reported more than 50,000 cases a day in the last few days of December 2020 and the first few days of 2021.
<p>Confirmed reinfection with SARS-CoV-2 variant VOC-202012/01</p> <p>Harrington, et al. 2021 (26)</p>	<ul style="list-style-type: none"> • Letter. • Confirmed case (78-year-old man) of reinfection with SARS-CoV-2 with the second episode due to the variant VOC-202012/01 of lineage B.1.1.7. • First infection occurred in the first wave of the pandemic and was a mild illness. • Eight months later reinfection with the new variant was confirmed and caused a critical illness.
<p>Emergence of a new SARS-CoV-2 variant in the UK</p> <p>Tang, et al. 2020 (8)</p>	<ul style="list-style-type: none"> • Letter. • A rapidly spreading variant in the UK has been reported in the UK, this variant is derived from the SARSCoV-2 20B/GR clade (lineage B.1.1.7) and contains multiple mutations, including a combination of the N501Y and the 69-70del mutations, both of which have been circulating,

Source	Summary
	<p>separately and independently, globally for many months previously.</p> <ul style="list-style-type: none"> • Early investigations suggest an increased transmissibility of up to 71% over and above the previous circulating strains of SARS-CoV-2, which may contribute 0.39-0.93 to the reproduction number estimates of the virus. • The risk of a more rapidly spreading virus is the potential impact in overwhelming healthcare services.
<p>Covid-19: What have we learnt about the new variant in the UK?</p> <p>Mahase 2020 (9)</p>	<ul style="list-style-type: none"> • News. • According to a review of the evidence by the UK's New and Emerging Respiratory Virus Threats Advisory Group, the rate of transmission of the new variant was 71% (95% confidence interval 67-75%), higher than for other variants, and that it may also have a higher viral load. • The first known case of this new variant was recorded on 20 September 2020. • The new variant is defined by 14 mutations resulting in amino acid changes and three deletions, some of which are believed to influence the virus's transmissibility in humans. • The World Health Organization has reported that one of the mutations identified (N501Y) has also been reported in South Africa. • Polymerase chain reaction (PCR) testing relies on three different assays, so the new variant shouldn't affect case numbers before two of the backup parts still detect the virus. • Peter Openshaw said 'We know that natural infection or vaccination will produce quite an array of antibody responses. Although it's predicted that some of the mutations that are present in the new variant will affect some of the sites that are recognised by the antibodies, it does not seem likely that it will affect all of them.' • People are working trying to get preliminary results. • Children appear to be more susceptible to this variant than previous. • The government has made no mention of any difference with respect to effectiveness of personal protective equipment.

Source	Summary
	<ul style="list-style-type: none"><li data-bbox="667 315 1442 421">• A handful of countries have confirmed cases of the new variant, including Australia, Denmark, Italy, Iceland, and the Netherlands.

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Source	Summary
<p>Covid-19: New coronavirus variant is identified in UK</p> <p>Wise 2020 (6)</p>	<ul style="list-style-type: none"> • The new variant is defined by a set of 17 changes or mutations, one of the most significant is an N501Y mutation. • As of 13 December 2020, 1,108 cases with this variant had been identified in the UK in nearly 60 different local authorities, although the true number will be much higher. • The new variant may be associated with the recent rise in cases in south-east England. • Mutations are expected and are a natural part of evolution. • Susan Hopkins said, 'There is currently no evidence that this strain causes more severe illness, although it is being detected in a wide geography, especially where there are increased cases being detected.'
<p>Pre peer review</p>	
<p>Inherent random fluctuations in COVID-19 outbreaks may explain rapid growth of new mutated virus variants</p> <p>Bodin, et al. 2021 (27)</p>	<ul style="list-style-type: none"> • Use of a simulation model calibrated to the inherent random fluctuating transmission pattern of COVID-19 to investigate what the probability may be for detecting more transmissible virus variants post facto. • The authors find that post facto identification of successful virus variants of SARS-COV-2, including the B.1.1.7 strain, are likely to exhibit growth rates that are substantially larger than the average growth rate. This finding has implications for interpreting growth rate and transmissibility of new virus variants.
<p>SARS-CoV-2 variant under investigation 202012/01 has more than twofold replicative advantage</p> <p>Grabowski, et al. 2021 (28)</p>	<ul style="list-style-type: none"> • Based on GISAID data, the authors show nearly exponential growth of the VUI-202012/01 to non-VUI-202012/01 genomes ratio in the five-week period from 19 October to 22 November 2020, with weekly growth rate of 2.31 (95% confidence interval: 2.08-2.57). • Assuming the serial interval of 6.73 days, the authors estimate the replicative advantage of VUI-202012/01 lineage as $2.31^{6.73/7} = 2.24$ (95% confidence interval: 2.03-2.48). • Based on the significant replicative advantage and the fact that London serves as major international transportation hub, the authors suggest that the VUI-202012/01 strain will likely become globally dominant, hindering containment of the COVID-19 epidemics prior to massive vaccinations.

Source	Summary
<p>Structure-function investigation of a new VUI-202012/01 SARS-CoV-2 variant</p> <p>Singh, et al. 2021 (29)</p>	<ul style="list-style-type: none"> • The authors thus chose to highlight crucial non-synonymous mutations and deletions occurring in SARS-CoV-2 VUI 202012/01 S, N and ORF8 proteins and their impact on structure-function of proteins. These proteins were selected owing to their curial role in host-viral interactome. • They conclude that mutations in S and ORF8 proteins can have significant impact on viral transmission and host immune responses. Coupling of viral pathogenesis and clinical data with long range molecular dynamics simulations can further aid in understanding structure function impacts of these mutations.
<p>Estimated transmissibility and severity of novel SARS-CoV-2 variant of concern 202012/01 in England</p> <p>Davies, et al. 2020 (30)</p>	<ul style="list-style-type: none"> • The authors fitted a two-strain mathematical model of SARS-CoV-2 transmission to observed COVID-19 hospital admissions, hospital and intensive care unit bed occupancy, and deaths; SARS-CoV-2 PCR prevalence and seroprevalence; and the relative frequency of VOC-202012/01 in the three most heavily affected NHS England regions (South East, East of England, and London). • They estimate that VOC 202012/01 is 56% more transmissible (95% credible interval across three regions 50-74%) than pre-existing variants of SARS-CoV-2. The authors surmise that the increase in transmissibility is likely to lead to a large increase in incidence, with COVID-19 hospitalisations and deaths projected to reach higher levels in 2021 than were observed in 2020, even if regional tiered restrictions implemented before 19 December 2020 are maintained. • No clear evidence that VOC-202012/01 results in greater or lesser severity of disease than pre-existing variants. • These estimates suggest that control measures of a similar stringency to the national lockdown implemented in England in November 2020 are unlikely to reduce the effective reproduction number to less than one, unless primary schools, secondary schools, and universities are also closed. • The authors project that large resurgences of the virus are likely to occur following easing of control measures. Thus, it may be necessary to greatly accelerate vaccine rollout to have an appreciable impact in suppressing the resulting disease burden.

Source	Summary
<p>Early empirical assessment of the N501Y mutant strains of SARS-CoV-2 in the United Kingdom, October to November 2020</p> <p>Leung, et al. 2020 (31)</p>	<ul style="list-style-type: none"> • 501Y variant 1: The authors estimated that the earlier 501Y lineage without amino acid deletion $\Delta 69/\Delta 70$ circulating mainly between early September to mid-November 2020 was 10% (6-13%) more transmissible than the 501N lineage. • 501Y variant 2: The currently dominant 501Y lineage with amino acid deletion $\Delta 69/\Delta 70$ circulating since late September was 75% (70-80%) more transmissible than the 501N lineage. Thus, the reproduction number would be 1.75 times that of the 501N strain. This variant has also become the dominant strain in England. • The authors discuss that these observations would imply more rapid and stringent control measures would be necessary to suppress spread. • The authors' phylogenetic analyses also show that the South African variant, with 501Y but not $\Delta 69/\Delta 70$, is genetically distant from 501Y variant 2 and has many mutations not shared with 501Y variant 2, suggesting the role of 501Y is more complex.
<p>Genomic characterisation of an emergent SARS-CoV-2 lineage in Manaus: preliminary findings</p> <p>Faria, et al. January 2021(16)</p>	<ul style="list-style-type: none"> • A report on genomic characterisation of the new variant P.1 detected in Manaus, Amazonas state, north Brazil. • The P.1 lineage was found in 42% of the samples collected from positive cases between 15 to 23 December 2020. It was not found in surveillance samples collected between March to November 2020, indicating the recent local transmission of the new variant. • The detected P.1 variant in Japan is suggested to be linked to Manaus. • Recent rapid increase in cases in locations where there had been high infection rates previously may potentially indicate an increased transmissibility or re-infection rates of the new variants, which needs urgent investigation.
<p>Grey literature</p>	
<p>SARS-CoV-2 variants</p> <p>World Health Organization 31 December 2020 (12)</p>	<ul style="list-style-type: none"> • 'Cluster 5', identified in Denmark in August and September 2020. <ul style="list-style-type: none"> ○ Variant linked to infection among farmed mink and subsequently transmitted to humans, and has a combination of mutations not previously observed. ○ There is concern that this variant may result in reduced virus neutralisation in humans, which could potentially

Source	Summary
	<p>decrease the extent and duration of immune protection following natural infection or vaccination.</p> <ul style="list-style-type: none"> ○ Danish authorities have identified only 12 human cases of the Cluster 5 variant in September 2020. ● VOC-202012/01, identified in the UK on 14 December 2020. <ul style="list-style-type: none"> ○ This variant contains 23 nucleotide substitutions and is not phylogenetically related to the SARS-CoV-2 virus circulating in the UK at the time the variant was detected. How and where SARS-CoV-2 VOC-202012/01 originated is unclear. ○ Preliminary epidemiologic, modelling, phylogenetic and clinical findings suggest that SARS-CoV-2 VOC-202012/01 has increased transmissibility. However, preliminary analyses also indicate that there is no change in disease severity (as measured by length of hospitalization and 28-day case fatality), or occurrence of reinfection between variant cases compared to other SARS-CoV-2 viruses circulating in the UK. ○ As of 30 December 2020, VOC-202012/01 variant has been reported in 31 other countries, territories or areas in five of the six World Health Organization regions. ● 501Y.V2, identified in South Africa on 18 December 2020. <ul style="list-style-type: none"> ○ Preliminary studies suggest the variant is associated with a higher viral load, which may suggest potential for increased transmissibility. ○ At this stage, there is no clear evidence of the new variant being associated with more severe disease or worse outcomes. ○ As of 30 December 2020, the 501Y.V2 variant from South Africa has been reported from four other countries to date.
<p>SARS-CoV-2 variant – United Kingdom of Great Britain and Northern Ireland</p> <p>World Health Organization 21 December 2020 (32)</p>	<ul style="list-style-type: none"> ● Variant under investigation, year 2020, month 12, variant 01 (VUI 202012/01), identified in the UK on 13 December 2020. <ul style="list-style-type: none"> ○ Preliminary reports by the UK are that this variant is more transmissible than previous circulating viruses, with an estimated increase of between 40 and 70% in transmissibility.

Source	Summary
	<ul style="list-style-type: none"> ○ At this stage there is not enough information to determine if this variant is associated with any change in severity of clinical disease, antibody response or vaccine efficacy. ○ The variant has been identified in several countries including Australia, Denmark, Italy, Iceland and the Netherlands.
<p>Emerging SARS-CoV-2 variants</p> <p>Centers for Disease Control and Prevention 3 January 2021 (2)</p>	<ul style="list-style-type: none"> ● B.1.1.7 lineage (a.k.a. 20B/501Y.V1 VOC-202012/01). <ul style="list-style-type: none"> ○ In the UK a new variant strain of SARS-CoV-2 (known as 20B/501Y.V1, VOC-202012/01, or B.1.1.7 lineage) emerged with an unusually large number of mutations. ○ This variant has since been detected in numerous countries around the world, including the United States and Canada. ● B.1.351 lineage (a.k.a. 20C/501Y.V2). <ul style="list-style-type: none"> ○ In South Africa, another variant of SARS-CoV-2 (known as 20C/501Y.V2 or B.1.351 lineage) emerged independently of the B.1.1.7 lineage. ○ This variant shares some mutations with the B.1.1.7 lineage. Cases attributed to this variant have been detected outside of South Africa. ● Currently, there is no evidence that these variants cause more severe illness or increased risk of death.
<p>New COVID-19 Variants</p> <p>Centers for Disease Control and Prevention 9 January 2021 (1)</p>	<ul style="list-style-type: none"> ● In the UK, a new variant has emerged with an unusually large number of mutations. This variant seems to spread more easily and quickly than other variants. Currently, there is no evidence that it causes more severe illness or increased risk of death. ● In South Africa, another variant has emerged independently of the variant detected in the UK. This variant seems to spread more easily and quickly than other variants. Currently, there is no evidence that it causes more severe illness or increased risk of death. ● Another variant recently emerged in Nigeria. Centers for Disease Control and Prevention, is monitoring this strain but, at this time, there is no evidence to indicate this variant is causing more severe illness or increased spread of COVID-19 in Nigeria.

Source	Summary
<p>COVID-19 UK variant VOC-202012/01 – what we know so far</p> <p>Public Health Ontario 29 December 2020 (11)</p>	<ul style="list-style-type: none"> • A new variant of SARS-CoV-2, VOC-202012/01 or lineage B.1.1.7, was identified in the UK. • The variant was detected after the UK observed a rapid increase in COVID-19 notification rates since late September 2020, with an ongoing increase as of December 2020. • Epidemiological findings and modelling data suggest that this strain may be more transmissible. Contact tracing and genomic sequencing data in the UK suggests that the secondary attack rate may be higher for cases with VOC-202012/01 compared to cases with other variants (15.1% vs 9.8%). Further laboratory-based investigations are underway to determine the impact of this strain on virulence and transmissibility. • Early analyses suggests that there is no increased risk for hospitalisation, 28-day case fatality, or reinfection with the UK variant. • The UK variant contains a high number of genomic mutations; however, laboratory-based assays and Health Canada-approved rapid tests currently available for COVID-19 detection are still likely to detect the UK variant. • To date, there is no indication that the vaccines will be less effective against this variant, although studies are ongoing.
<p>Australian Health Protection Principal Committee (AHPPC) statement on new variant of the virus that causes COVID-19</p> <p>Australian Government Department of Health 21 December 2020 (24)</p>	<ul style="list-style-type: none"> • A statement from the Australian Health Protection Principal Committee on the UK variant of the virus that causes COVID-19. • There is no evidence that this variant of the virus causes more severe disease. The vaccines procured for Australia induce a broad immune response to protect individuals. There is no evidence at this stage that these vaccines would not be effective against the UK variant.
<p>Report 42 - Transmission of SARS-CoV-2 lineage B.1.1.7 in England: insights from linking epidemiological and genetic data</p> <p>Imperial College London 31 December 2020 (33)</p>	<ul style="list-style-type: none"> • The SARS-CoV-2 lineage B.1.1.7, VOC- 202012/01, originated in the UK. • Epidemiological evidence for this variant of concern having a transmission advantage from several perspectives. <ul style="list-style-type: none"> ○ First, whole genome sequence data collected from community-based diagnostic testing provides an indication of changing prevalence of different genetic

Source	Summary
	<p>variants through time. Phylodynamic modelling additionally indicates that genetic diversity of this lineage has changed in a manner consistent with exponential growth.</p> <ul style="list-style-type: none"> ○ Second, changes in variant of concern frequency inferred from genetic data correspond closely to changes inferred by S-gene target failures in community-based diagnostic PCR testing. ○ Third, growth trends in S-gene target failures and non-S-gene target failures case numbers at local area level across England show that the variant of concern has higher transmissibility than non-variant of concern lineages, even if the variant of concern has a different latent period or generation time. Available S-gene target failures data indicate a shift in the age composition of reported cases, with a larger share of under 20-year-olds among reported variant of concern than non-variant of concern cases.

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Source	Summary
<p>Risk assessment: risk related to spread of new SARS-CoV-2 variants of concern in the EU/EEA</p> <p>European Centre for Disease Prevention and Control, 29 December 2020 (13)</p>	<ul style="list-style-type: none"> • This risk assessment presents the latest available information on the recent emergence of two variants of potential concern, VOC-202012/01 discovered in the UK and another variant, 501.V2 identified in South Africa. • European Centre for Disease Prevention and Control assesses that the probability of SARS-CoV-2 VOC-202012/01 and 501.V2 being introduced and further spread in the European Union and European Economic Area is currently high. • Although there is no information that infections with these strains are more severe, due to increased transmissibility the impact of COVID-19 disease in terms of hospitalisations and deaths is assessed as high, particularly for those in older age groups or with co-morbidities. The overall risk associated with the introduction and further spread of SARS-CoV-2 VOC-202012/01 and 501.V2 is therefore assessed as high.
<p>NERVTAG meeting on SARS-CoV-2 variant under investigation VUI-202012/01</p> <p>New and Emerging Respiratory Virus Threats Advisory Group 2020 (10)</p>	<ul style="list-style-type: none"> • Brief summary of New and Emerging Respiratory Virus Threats Advisory Group opinion. • New and Emerging Respiratory Virus Threats Advisory Group has moderate confidence that VUI-202012/01 demonstrates a substantial increase in transmissibility compared to other variants. Growth rate from genomic data: which suggest a growth rate of VUI-202012/01 that is 71% (95% confidence interval: 67-75%) higher than other variants. • Studies of correlation between R-values and detection of the variant: which suggest an absolute increase in the R-value of between 0.39 to 0.93. • New and Emerging Respiratory Virus Threats Advisory Group concluded that there are currently insufficient data to draw any conclusion on: <ul style="list-style-type: none"> ○ underlying mechanism of increased transmissibility (e.g. increased viral load, tissue distribution of virus replication, serial interval etc.) ○ the age distribution of cases ○ disease severity ○ antigenic escape.

Source	Summary
<p data-bbox="145 311 584 450">Rapid increase of a SARS-CoV-2 variant with multiple spike protein mutations observed in the United Kingdom</p> <p data-bbox="145 472 531 577">European Centre for Disease Prevention and Control, 29 December 2020 (34)</p>	<ul style="list-style-type: none"> <li data-bbox="667 315 1034 344">• Threat assessment brief. <li data-bbox="667 367 1461 510">• Given that there is currently a lack of evidence to indicate the extent to which the new virus variant is spread outside the UK, timely efforts to prevent and control its spread are needed, and include the following. <ul style="list-style-type: none"> <li data-bbox="687 533 1461 779">○ Public health authorities and laboratories are urged to analyse and sequence virus isolates in a timely manner to identify cases of the new variant. People with an epidemiological link to cases with the new variant or travel history to areas known to be affected should be identified immediately to test, isolate and follow up their contacts in order to stop the spread of the new variant. <li data-bbox="687 801 1461 972">○ If cases infected with this new SARS-CoV-2 variant or other new SARS-CoV-2 variants of potential concern are identified, countries should notify through the Early Warning and Response System of the European Union. <li data-bbox="687 994 1461 1164">○ The importance of strict adherence to non-pharmaceutical interventions according to national policies needs to be communicated to the public, and in particular guidance on the avoidance of non-essential travel and social activities should be stressed. <li data-bbox="687 1187 1461 1330">○ Laboratories should review the PCR performance and drop-out of the S-gene. PCR could be used as an indicator for cases with the new variant for further sequencing and investigation. <li data-bbox="687 1352 1461 1563">○ Suspected cases of COVID-19 reinfection should be followed up, closely accompanied by sequencing respective virus isolates from these cases. Similarly, cases with treatment failures using convalescent plasma or monoclonal antibodies should be further studied. <li data-bbox="667 1585 1461 1800">• With the implementation of vaccination, close monitoring of COVID-19-vaccinated individuals needs to be ensured to identify possible vaccination failure and breakthrough infections. Virus isolates from these cases should be sequenced and characterised genetically and antigenically.

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Source	Summary
<p>Risk related to the spread of new SARS-CoV-2 variants of concern in the EU/EEA – first update</p> <p>European Centre for Disease Prevention and Control, 21 January 2021(3)</p>	<ul style="list-style-type: none"> • This rapid risk assessment and first update presents the latest available information on the recent emergence of three variants of potential concern, VOC-202012/01 discovered in the UK, 501.V2 identified in South Africa and P.1variant identified in Brazil. • European Centre for Disease Prevention and Control assesses that the probability of SARS-CoV-2 VOC-202012/01, 501.V2 and P.1 being introduced and spread in the community in EU/EEA is very high. • Due to increased transmissibility of the new variants, the impact of COVID-19 disease in terms of hospitalisations and deaths is assessed as high, particularly for those in older age groups or with co-morbidities. • The overall risk associated with the introduction and community spread of new variants is assessed as being high/very high. • Variant of concern (VOC) 202012/01 <ul style="list-style-type: none"> ○ First identified in the UK in December 2020. As of 19 January 2021, it was identified in 23 countries in EU/EEA and 60 countries around the world. ○ A recent Danish modelling study (January 2021) estimates that the new variant was 36% more transmittable than the other variants. ○ Currently there is no indication of its association with more severe clinical presentations compared to other pre-existing strains. ○ Currently there is no evidence to indicate the new variant changes the risk of reinfection when comparing to non-variant viruses. • Variant 501Y.V2 <ul style="list-style-type: none"> ○ First identified in South Africa in December 2020. As of 19 January, it was identified in 10 EU/EAA countries and 23 countries around the world, including Australia. ○ Modelling studies estimate that the variant is 50% more transmittable than previously circulating variants in South Africa (14) ○ There is no clear evidence to indicate increased disease severity associated with this variant (14) ○ There some concerns that this variant could be associated with increased risk of reinfection or

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Source	Summary
	<p>vaccine breakthrough infections due to the combination of amino acid changes in the variant,</p> <ul style="list-style-type: none"> • New SARS-CoV-2 variant P.1 <ul style="list-style-type: none"> ○ First reported in Japan on 10 January 2021 and found in returning travellers from Brazil. South Korea reported one case with the new variant in a returned traveller from Brazil on 18th January. To date, it was not reported in EU/EAA countries. ○ Information on the epidemiology of this variant is very limited. Currently there is no evidence available to indicate a change in transmissibility. Increase in transmissibility could be possible due to presence of amino acid change. ○ No evidence available on the changes in infection severity.

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Source	Summary
<p data-bbox="145 311 539 443">Estimates of severity and transmissibility of novel South Africa SARS-CoV-2 variant 501Y.V2</p> <p data-bbox="145 510 469 591">Pearson, et al.(14) January 2021 (Pre-print)</p>	<ul data-bbox="667 315 1465 792" style="list-style-type: none"> • A pre-print commentary on f novel South Africa SARS-CoV-2 variant 501Y.V2 • Adapting the underlying model from the UK study(30) and using a less data-intensive approach, authors estimate that 501Y.V2 is 50% more transmissible (95% credible interval 20-113%) than pre-existing variants of SARS-CoV-2 and evades 21% (95% credible interval 11-36%) of previously acquired immunity. • There is some evidence of a change in disease severity, although there is substantial uncertainty. • The results suggest substantial challenges to controlling SARS-CoV-2 in early 2021.

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Table 2 New variants and existing vaccine efficacy

Source	Summary
Peer reviewed sources	
<p>Genetic variants of SARS-CoV-2 — what do they mean?</p> <p>Lauring, et al. January 2021(5)</p>	<ul style="list-style-type: none"> • Viewpoint. • Genomic surveillance of SARS-CoV-2 variants has largely focused on mutations in the spike glycoprotein. There is interest in whether these mutations mediate escape from host antibodies and could potentially compromise vaccine effectiveness. • At this point, strong selection of a variant at the population level is probably not driven by host antibody because there are not sufficient numbers of immune individuals. • Because current vaccines provoke an immune response to the entire spike protein, effective protection may still occur despite a few changes at antigenic sites in SARS-CoV-2 variants. • It is important to consider both the magnitude of the change in neutralisation and the number of serum samples evaluated, as many mutations in spike might affect neutralisation by convalescent sera. • One issue is that viral glycoproteins are subject to evolutionary trade-offs, so it is possible that mutations in spike that are ‘good’ for the virus right now could in the future make it less fit in the context of population-level immunity.
<p>A SARS-CoV-2 vaccine candidate would likely match all currently circulating variants</p> <p>Dearlove, et al. 2020 (35)</p>	<ul style="list-style-type: none"> • This study was published in August 2020 before the first reported case of the new variant; however, the publication is of relevance to this research question and therefore included. • 18,514 SARS-CoV-2 sequences sampled since December 2019 were analysed. • In the immunogenic spike protein, the D614G mutation has become consensus, yet there is no evidence of mutations affecting binding to the ACE2 receptor. • The results suggest that the limited diversity seen in SARS-CoV-2 should not preclude a single vaccine from providing global protection.
<p>Covid-19: UK approves Oxford vaccine as cases of new variant surge</p>	<ul style="list-style-type: none"> • BMJ news.

Source	Summary
<p>Mahase 2020 (36)</p>	<ul style="list-style-type: none"> • The UK’s medicines regulator has approved the Oxford and AstraZeneca COVID-19 vaccine. • The approval of the new vaccine comes as most areas in the UK were moved up into higher tiers of restrictions. • More than 53,000 new COVID-19 cases were reported across the UK on 29 December 2020, most of them the new variant called B.1.1.7.
<p>Covid-19: What have we learnt about the new variant in the UK? Mahase 2020 (9)</p>	<ul style="list-style-type: none"> • BMJ news. • The message from experts speaking at a Science Media Centre briefing on COVID-19 was that the new variant was unlikely to make vaccines ineffective.
<p>Covid-19: New coronavirus variant is identified in UK Wise 2020 (6)</p>	<ul style="list-style-type: none"> • BMJ news. • The UK variant has mutations to the spike protein that the three leading vaccines are targeting. • However, vaccines produce antibodies against many regions in the spike protein, so it is unlikely that a single change would make the vaccine less effective. • The vaccine may need to be altered over time as more mutations occur, as happens with the seasonal flu virus.
<p>Could new COVID variants undermine vaccines? Labs scramble to find out Callaway 2021 (37)</p>	<ul style="list-style-type: none"> • Nature news. • Scientists are scrambling to understand the UK and South African SARS-CoV-2 variants and the significance for the effectiveness of current vaccines. • There is concern that the variants could weaken immune responses triggered by vaccines and previous infection.
<p>Pre peer review</p>	
<p>Impact of B.1.1.7 variant mutations on antibody recognition of linear SARS-CoV-2 epitopes Haynes, et al. 2021 (20)</p>	<ul style="list-style-type: none"> • 579 COVID-19 patients’ samples collected between March and July 2020. • Authors examined the effects of non-synonymous mutations harboured by the circulating B.1.1.7 strain on linear antibody epitope signal for spike glycoprotein and nucleoprotein. • The data suggest that the mutations would not result in immune evasion of linear epitopes for a large majority of these COVID patients.

Source	Summary
<p>Viral variants and vaccinations: if we can change the COVID-19 vaccine... should we?</p> <p>Bewick 2021 (38)</p>	<ul style="list-style-type: none"> • Use of a stochastic simulation to determine when it is better to target a newly emerged viral variant and when it is better to target the dominant but potentially less transmissible strain. • The results suggest that it is almost always better to target the faster spreading strain, even when the initial prevalence of this variant is much lower. • The author surmises that: <ul style="list-style-type: none"> ○ in scenarios where targeting the slower spreading variant is best, all vaccination strategies perform relatively well, meaning that the choice of vaccination strategy has a small effect on public health outcomes ○ in scenarios where targeting the faster spreading variant is best, use of vaccines against the faster spreading viral variant can save many lives.
<p>Neutralization of N501Y mutant SARS-CoV-2 by BNT162b2 vaccine-elicited sera</p> <p>Xie, et al. 2021 (22)</p>	<ul style="list-style-type: none"> • The authors generated isogenic N501 and Y501 SARS-CoV-2 (similar to the rapid spreading UK and South African variants that share the spike N501Y substitution). • They then used sera of 20 participants in a previously reported trial of the mRNA-based COVID-19 vaccine BNT162b2, and found their sera had equivalent neutralising titers to the N501 and Y501 viruses.
<p>BNT162b2 induces SARS-CoV-2-neutralising antibodies and T cells in humans</p> <p>Sahin, et al. 2020 (39)</p>	<ul style="list-style-type: none"> • To facilitate prospective surveillance for viral evolution, the authors mapped the impact on convalescent serum antibodies by mutations to the spike's receptor-binding domain, the main target of serum neutralising activity. • They found that binding by polyclonal serum antibodies is affected by mutations in three main epitopes in the receptor-binding domain, but there is substantial variation in the impact of mutations both among individuals and within the same individual over time. • The mutations that most reduce antibody binding usually occur at just a few sites in the domain's receptor binding motif. The most important site is E484, where neutralisation by some sera is reduced more than 10-fold by several mutations, including one in emerging viral lineages in South Africa and Brazil. (E484K is present in recently described lineage in the South African S.501Y.V2 variant). • The serum escape maps developed by the authors makes it possible to begin to assess which circulating receptor-

Source	Summary
	<p>binding domain mutations are likely to have the greatest impact on human immunity. In particular, emerging lineages in South Africa and Brazil carrying the E484K mutation will have greatly reduced susceptibility to neutralisation by the polyclonal serum antibodies of some individuals. In contrast, the N501Y mutation present in the UK lineage is unlikely to greatly affect neutralisation by most human sera, although it could contribute to increased viral titer or enhanced transmissibility.</p>
<p>SARS-CoV-2 501Y.V2 escapes neutralization by South African COVID-19 donor plasma</p> <p>Wibmer, et al. 19 January 2021(15)</p>	<ul style="list-style-type: none"> • Authors describe that 501Y.V2 included nine changes in the spike protein. • The spike mutations in new SARS-CoV-2 variant lineage are found to escape two major classes of monoclonal antibodies and showed high levels of resistance to convalescent plasma/sera. • Authors suggests that the 501Y.V2 lineage of the SARS-CoV-2 is largely resistant to neutralizing antibodies formed by being infected with previously circulating lineages and therefore poses significant re-infection risk. It may also reduce effectiveness of vaccines which are based on immune responses to spike, requiring rapidly adaptable vaccine design platforms.

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Source	Summary
Grey literature	
<p>Episode #20 - COVID-19 - variants & vaccines World Health Organization 8 January 2021 (19)</p>	<ul style="list-style-type: none"> • The World Health Organization’s <i>Science in 5</i> podcast with World Health Organization’s Chief Scientist Dr Soumya Swaminathan discussing the new variants of SARS-CoV-19 and whether current vaccines provide protection. • Most scientists believe that vaccines currently in development and a couple that have been approved should provide protection against variants as the vaccines elicit a fairly broad immune response. • Focus should continue to be on reducing transmission through quarantining, isolation, physical distancing, masks, hand hygiene.
<p>Highly infectious COVID variants spur calls to shut Australia’s borders Woodley 2021 (40)</p>	<ul style="list-style-type: none"> • The Royal Australian College of General Practitioners news. • New SARS-CoV-2 variants are thought to be more infectious and may potentially affect vaccine efficacy.
<p>Mutation in SARS-CoV-2 variant does not affect vaccine: study Grens 2021 (41)</p>	<ul style="list-style-type: none"> • Summarises results from a study showing that serum samples from 20 individuals who received the Pfizer-BioNTech vaccine protected against the N501Y mutation present in the UK and South African variants. • Pfizer has previously tested its vaccine against 15 other mutations with no significant impact. • However, scientists are concerned about the E484K mutation in the South African variant which is still to be tested.
<p>SARS-CoV-2 variants World Health Organization 31 December 2020 (12)</p>	<ul style="list-style-type: none"> • This <i>Disease Outbreak News</i> article outlines the SARS-CoV-2 variants and ongoing studies investigating the neutralisation activity of sera from recovered and vaccinated patients against these variants to assess the impact on vaccine performance. • World Health Organization advises countries to increase routine systematic sequencing of SARS-CoV-2 viruses to better monitor the emergence of variants.
<p>Emerging SARS-CoV-2 variants Centers for Disease Control and Prevention 3 January 2021 (2)</p>	<ul style="list-style-type: none"> • There is no evidence that the UK or South African variants have any impact on vaccine efficacy.

Source	Summary
<p>Statement on variants of the SARS-CoV-2 virus</p> <p>Moderna 23 December 2020 (23)</p>	<ul style="list-style-type: none"> • Press release from Moderna on the efficacy of their vaccine against the SARS-CoV-2 UK variant. • Tests based on sera from animals and humans vaccinated with the Moderna vaccine have shown the vaccine to remain equally effective against previous variants of the SARS-CoV-2 virus. • Moderna expects that the Moderna vaccine and vaccine-induced immunity would be protective against the UK variant.
<p>Rapid increase of a SARS-CoV-2 variant with multiple spike protein mutations observed in the United Kingdom</p> <p>European Centre for Disease Control and Prevention 20 December 2020 (34)</p>	<ul style="list-style-type: none"> • This <i>Threat Assessment Brief</i> summarises the findings on the UK variant, VUI 202012/01. • Vaccinated patients are monitored for reinfection and infections. • Based on the number and location of spike protein mutations in this variant, some reduction of neutralisation by antibodies is expected, however there is no evidence yet to suggest increased risk for reinfection or lower vaccine effectiveness. • There is no phenotypic data available for the new variant. • There is no data available on the ability of vaccines under development to neutralise this variant. • Most of the new candidate vaccines are based upon the spike protein sequence so monitoring changes in the spike protein among circulating SARS-CoV-2 strains is essential. • National public health authorities are advised to: <ul style="list-style-type: none"> ○ closely monitor vaccinated individuals for vaccination failure and breakthrough infections ○ develop processes for adapting vaccine strain recommendations and reassessing vaccine composition and strategy.
<p>Risk related to spread of new SARS-CoV-2 variants of concern in the EU/EEA</p> <p>European Centre for Disease Control and Prevention 29 December 2020 (13)</p>	<ul style="list-style-type: none"> • This <i>Rapid Risk Assessment</i> summarises the available information in the UK and South African variants. • There is not enough information to determine whether the variants are a risk to vaccine match and effectiveness.

Source	Summary
<p>Australian Health Protection Principal Committee (AHPPC) statement on new variant of the virus that causes COVID-19</p> <p>Australian Government Department of Health 22 December 2020 (24)</p>	<ul style="list-style-type: none"> • A statement from the Australian Health Protection Principal Committee on the UK variant (VUI 202012/01) of the virus that causes COVID-19. • The vaccines procured for Australia induce a broad immune response to protect individuals and there is no evidence at this stage that these vaccines would not be effective against the UK variant.
<p>An in vitro study shows Pfizer-BioNTech COVID-19 vaccine elicits antibodies that neutralize SARS-CoV-2 with a mutation associated with rapid transmission</p> <p>Pfizer 8 January 2021 (21)</p>	<ul style="list-style-type: none"> • Press release from Pfizer and BioNTech on results of an in vitro study of the effectiveness of the Pfizer-BioNTech vaccine for the UK and South African SARS-CoV-2 variants. • The two variants are different but share the N501Y mutation. • The sera of people who had received the Pfizer-BioNTech COVID-19 vaccine neutralised the virus with the mutations as well as they neutralised the virus without the mutation. • The experiment did not include the full set of spike mutation found on the variants, however the results indicate that the N501Y mutation does not create resistance to the vaccine induced immune responses. • Further data are needed to monitor the Pfizer-BioNTech COVID-19 vaccine’s effectiveness in preventing COVID-19 caused by new virus variants.

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Appendix

PubMed search terms

Initial search: (((SARS-CoV-2 AND Variant*) AND (UK OR United Kingdom OR South Africa)) OR (SARS-CoV-2[ti] AND Variant*[ti])) AND ((2020/09/1:2021/1/31[pdat]))

Living evidence: (("2019-nCoV"[Title/Abstract] OR "ncov*" [Title/Abstract] OR "covid-19"[Title/Abstract] OR "covid19"[Title/Abstract] OR "covid-19"[Title/Abstract] OR "coronavirus"[MeSH Terms] OR "coronavirus"[Title/Abstract] OR "sars-cov-2"[Title/Abstract] OR "severe acute respiratory syndrome coronavirus 2"[Supplementary Concept])) AND (variant*)

Note for living evidence search strings may be tweaked as the topic area further develops.

Google and MedRxiv search terms

Google: COVID-19 variants, COVID-19 variant UK, COVID-19 variant South Africa, SARS-CoV-2 Variants, COVID-19 variants vaccine, sars-cov-2 variants vaccine

MedRxiv: 50 pages of MedRxiv and BioRxiv COVID-19 database:

<https://connect.medrxiv.org/relate/content/181>

Using terms 'variant' and 'strain'

Inclusion and exclusion criteria

Inclusion	Exclusion
<ul style="list-style-type: none"> Review articles, empirical studies, commentaries, editorials, letters, news articles if published in scientific journals Publications relevant to new variants of SARS-CoV-2 (UK B.1.1.7 and South African 501Y.V2) 	<ul style="list-style-type: none"> News articles not published in scientific journals Full text not available

Living evidence methods

Living evidence tables are monitored and updated daily. To monitor the evidence, we have:

- Set up a PubMed search to receive automatic alerts daily
- Search the CIU daily evidence digest database daily
- Monitor grey literature/policy decisions through grey literature searching

Updates

Original search	Updates
11 January 2021	
22 January 2021	<ul style="list-style-type: none"> Updated with new data based on the European Centre for Disease Prevention and Control risk assessment.(3)
5 February 2021	<ul style="list-style-type: none"> Updated to include link to living evidence tables and living evidence methods.

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