

# Risk related to the spread of new SARS-CoV-2 variants of concern in the EU/EEA – first update

21 January 2021

## Summary

Viruses constantly change through mutation and variations in the SARS-CoV-2 virus, due to evolution and adaptation processes, have been observed worldwide. While most emerging mutations will not have a significant impact on the spread of the virus, some mutations or combinations of mutations may provide the virus with a selective advantage, such as increased transmissibility or the ability to evade the host immune response. In this update we report new information on the spread of three virus variants (VOC 202012/01, 501Y.V2 and variant P.1). These variants are considered to be of concern because of mutations which have led to increased transmissibility and deteriorating epidemiological situations in the areas where they have recently become established.

Based on the new information, the risk associated with the introduction and community spread of variants of concern has been increased to **high/very high** and the options for response have been adjusted to the current situation.

## Variants of concern

VOC 202012/01 was first identified as being of concern in the south of the United Kingdom (UK) in December 2020. The first sample in which it could be identified has been traced back to September 2020. Since then, it has become the predominant variant circulating in the UK. It is characterised by a significantly increased transmissibility, which has contributed to increases in incidence, hospitalisations and pressure on the healthcare system since the second half of December 2020. The UK has implemented stricter non-pharmaceutical interventions (NPIs) to reduce transmission. Preliminary studies indicate that there is no evidence that VOC 202012/01 is associated with a significantly different infection severity or that it disproportionately affects certain age groups more than the previous circulating viruses. However, as a result of the increased incidence, by January 2021 the UK had reported the highest daily COVID-19 mortality since the start of the pandemic. Ireland, where local circulation of VOC 202012/01 has also recently been identified, has experienced an increase in case numbers and hospitalisations, growing pressure on the health system and has also had to implement stricter NPIs. Denmark has also observed community transmission of VOC 202012/01 and in response has strengthened NPIs and prolonged measures throughout January 2021.

The variant 501Y.V2 was first identified in South Africa in December 2020, where it is now the most prevalent variant. Preliminary results indicate that this variant may also have an increased transmissibility. However, as for VOC 202012/01, at this stage it is uncertain whether the 501Y.V2 variant causes a change in disease severity. As per 19 January 2021, 501Y.V2 has been identified in 10 EU/EEA countries. One cluster of this variant is currently being investigated in France. In addition to France, Israel and the UK have also reported

cases or clusters of non-travel-related 501Y.V2 cases. The remaining cases identified in the EU/EEA have mostly been travel-related, but not only from South Africa.

The P.1 variant has so far only been identified in Brazil, and in travellers from Brazil (mostly from the Amazonas State) reported in Japan and South Korea. The capital of Amazonas, Manaus, is currently experiencing an upsurge in COVID-19 cases, putting significant pressure on the healthcare system.

The under-ascertainment of SARS-CoV-2 infections in general, and the very small proportion of cases undergoing sequencing in most EU/EEA countries, may lead to a large under-ascertainment of the true number of VOC 202012/01, 501Y.V2 and P.1 infections, and other potential variants that may contribute to rapid epidemiological changes.

### Risks associated with virus variants

ECDC assesses the probability of the introduction and community spread of variants of concern in the EU/EEA as **very high** due to their increased transmissibility. Such an increased transmissibility is likely to lead to an increased number of infections. This, in turn, is likely to lead to higher hospitalisation and death rates across all age-groups, but particularly for those in older age groups or with co-morbidities. Consequently, stricter NPIs are needed to reduce transmission and relieve the pressure on healthcare systems. Therefore, the impact of introduction and community spread is considered to be **high**. The overall risk associated with the introduction and community spread of variants of concern is therefore assessed as being **high/very high**.

### Options for response

Member States should continue to monitor local changes in transmission rates or infection severity to identify and assess the circulation and impact of variants. In order to detect introductions of known variants, as well as the emergence of new variants, Member States need to increase the level of surveillance and sequencing of a representative sample of community COVID-19 cases.

Member States should prepare laboratories for increased testing turnover. Laboratories should consider implementing diagnostic pre-screening for variants of concern (e.g. N501Y and deletion 69-70), ensure resources are available to manage an increasing number of requests for detection and characterisation of COVID-19 samples, and increase sequencing capacity by making use of all possible sequencing capacity from clinical, diagnostic, academic and commercial laboratories across different sectors.

In order to control the spread and impact of the SARS-CoV-2 emerging variants with increased transmissibility, a combination of compliance with NPIs - including potentially stricter NPIs than those currently in place - and strengthened case detection with contact tracing is required. Since the population groups driving transmission will not be targeted with vaccination for some months, Member States are recommended to be very cautious about relaxing NPIs. Furthermore, in light of the evidence of substantially higher transmissibility of the new variants of concern, national authorities should rather be ready to enforce even stricter measures, communicating and engaging with the population to encourage compliance. In general, contact tracing should be reinforced, and its scope widened in relation to cases suspected to be infected with new variants.

In order to slow down the importation and spread of the new SARS-CoV-2 variants of concern, ECDC recommends that non-essential travel should be avoided. In addition to recommendations against non-essential travel, and restrictions on travel for those infected, travel measures such as the testing and quarantining of travellers should be maintained, in particular for travellers from areas with a higher incidence of the new variants. If sequencing is inadequate to exclude the possibility of a higher incidence of the new variants, as per ECDC guidance on genomic sequencing, proportionate travel measures should also be considered from areas where there is a continued high level of community transmission.

Member States should prepare their healthcare systems for a further escalation in demand due to the increased transmissibility of the new variants of concern.

Member States are encouraged to accelerate the pace of vaccination for high-risk groups, such as the elderly and healthcare workers. At this stage, vaccination should be focused on protecting those most at risk from severe disease, and reducing morbidity, mortality and the burden on healthcare systems. It is important to use the available vaccines to provide protection for those who are most vulnerable and for key workers against the current circulating virus variants in the EU/EEA, and hopefully also against one or all of the new variants of concern. Assessment of VOC 202012/01 suggests cross-immunity is present, while investigations into the other variants of concern are still on-going. Member States should monitor vaccine effectiveness for these new variants. Breakthrough infections should be monitored, carefully investigated (including sequencing the virus variant causing breakthrough infection), and reported to public health and regulatory agencies to allow for an overview at country and EU-level. In addition, Member States should explore options for optimal use of the limited number of vaccine doses.

This risk assessment presents the latest available information on the recent emergence of three variants of concern, VOC 202012/01 identified in the United Kingdom (UK), 501Y.V2 identified in South Africa, and P.1 identified in Brazil, Japan and South Korea.

# Event background

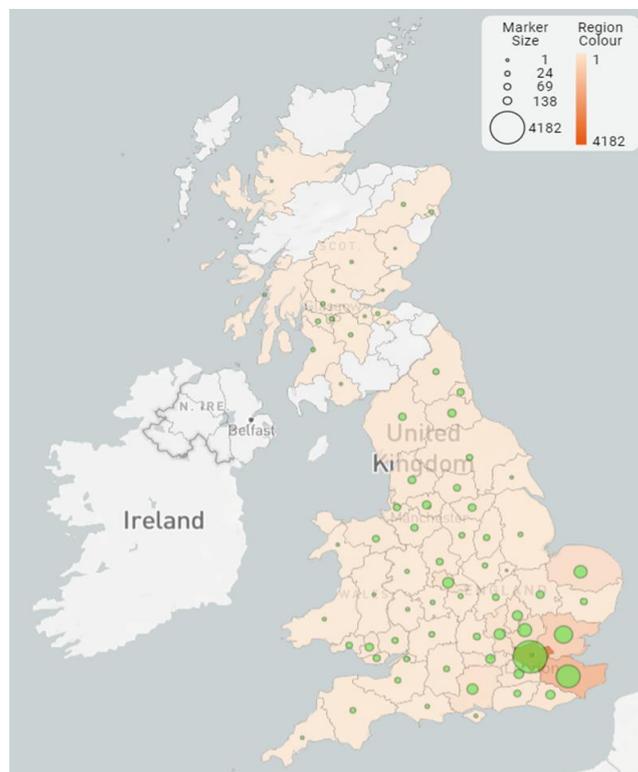
## Variant of concern (VOC) 202012/01

In December 2020, the UK faced a rapid increase in COVID-19 notification rates (Figure 1, Annex 1). The seven-day notification rate rapidly increased from 162 cases per 100 000 population at the end of week 49, to 345 for week 51 and 595 for week 53 of 2020 (corresponding to a 3.7-fold increase in week 53 compared to week 49 2020).

Genomic analysis of viral sequence data reported in the UK identified a large proportion of sequenced cases in the regions of the South East, the East and London which belonged to a new single phylogenetic cluster [1]. The rapid increase in COVID-19 cases overall was associated with the emergence of SARS-CoV-2 VOC 202012/01 (Variant of Concern, year 2020, month 12, variant 01, previously designated VUI, Variant under Investigation) in these regions in November 2020. The first known instance of VOC 202012/01 infection was retrospectively identified in a case from 20 September 2020 in the UK [2].

The number and proportion of VOC 202012/01 cases confirmed by sequencing has also increased in recent weeks and cases have been identified in most regions of the UK (Figure 1). As of 19 January 2021, according to media and official sources, approximately 16 800 VOC 202012/01 cases had been identified in the UK.

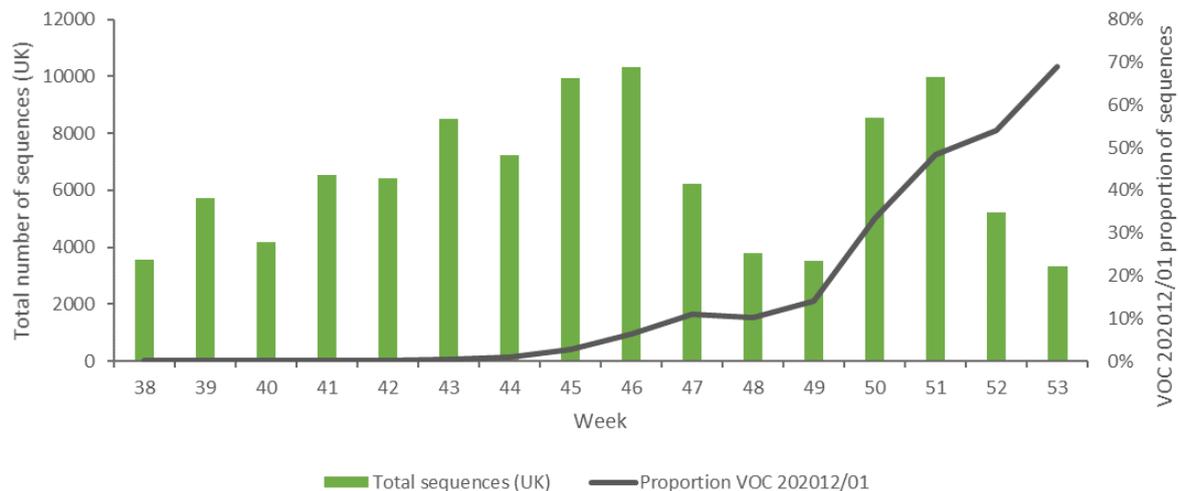
**Figure 1. Distribution of VOC 202012/01 cases confirmed by sequencing, UK, 1 September 2020 to 9 January 2021**



*Note: Map adapted from COVID-19 Genomics UK (COG-UK) Consortium available at <https://beta.microreact.org/project/r8vBmatkC9mcfjJ6bUtNr-cog-uk-2021-01-09-sars-cov-2-in-the-uk/> [3]. Period: 1 Sep 2020 – 9 Jan 2021. COG-UK data. Caution should be taken when interpreting these data due to potential sampling biases and delay between sample collection and sequencing in recent weeks.*

The overall proportion of VOC 202012/01 among all uploaded virus sequences from the UK reported to the GISAID EpiCoV database [2] has increased substantially, particularly since week 49/2020 (Figure 2).

**Figure 2. Proportion of UK SARS-CoV-2 sequences classified as VOC 202012/01 per week, and total sequences per week from the UK**



*Weeks 1 and 2 of 2021 have been omitted due to very few sequences being available.*

*Source: GISAID EpiCov database. More detailed national analysis of sequences from the UK is available from the COVID-19 Genomics UK Consortium [4].*

On 19 December 2020, in response to the increase in cases, the nations of the UK announced stricter measures to be applied from 20 December 2020 and in the weeks that followed [5,6].

On 22 December 2020, the European Commission adopted a 'Recommendation on a coordinated approach to travel and transport in response to the SARS-CoV-2 variant observed in the UK' [7]. The aim of the Commission Recommendation was to have a coordinated approach in order to ensure free movement during the pandemic, while discouraging all non-essential travel to limit the further spread of the new variants [8].

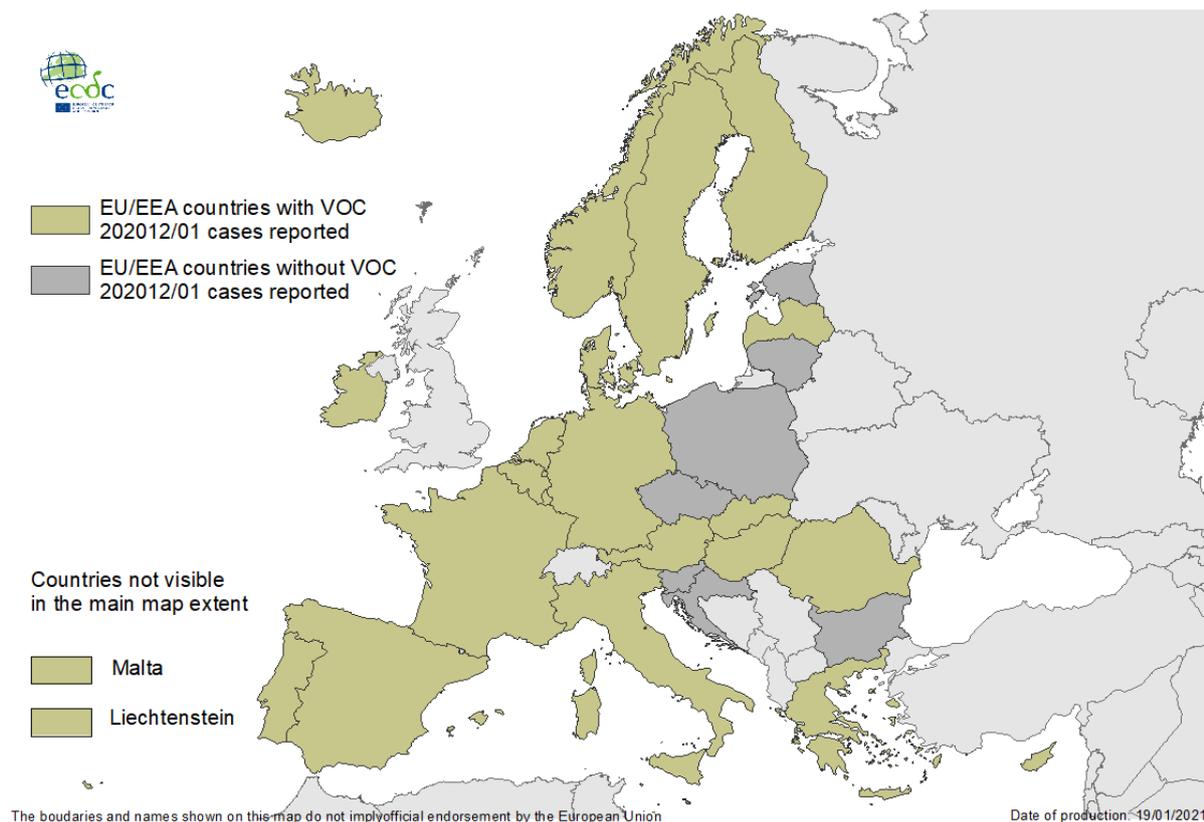
### Detection of the VOC 202012/01 variant outside of the UK

As of 19 January 2021, according to media and official sources, in addition to the UK approximately 2 000 cases of the variant VOC 202012/01 had been identified in 60 other countries.

In the EU/EEA, about 1 300 cases have been identified in 23 countries: Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Luxembourg, Malta, Netherlands, Norway, Portugal, Romania, Slovakia, Spain and Sweden.

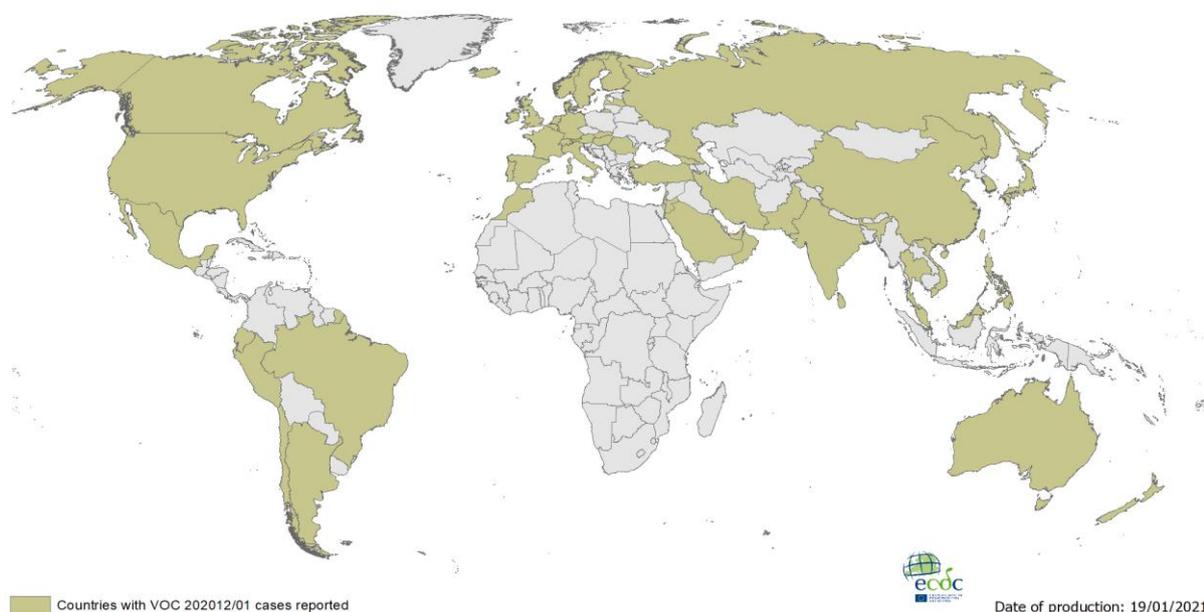
Outside the EU/EEA, approximately 700 cases have been identified in 37 countries (Figure 4). After the UK, the three non-EU/EEA countries reporting most cases are Israel (147), India (109) and the United States (92).

**Figure 3. Countries reporting cases of VOC 202012/01 in the EU/EEA, as of 19 January 2021**



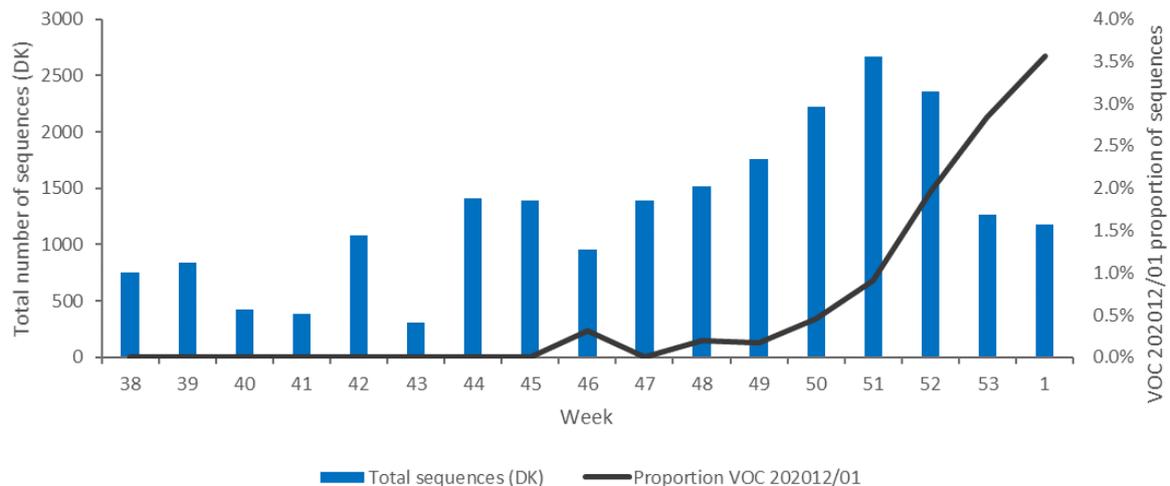
*Note: EU/EEA countries with VOC 202012/01 cases on the map may not represent the full geographical extent of the variant spread in the EU/EEA*

**Figure 4. Countries reporting cases of VOC 202012/01 worldwide, as of 19 January 2021**



In Denmark an extensive sequencing programme is underway. Sequencing data reported by Denmark to GISAID EpiCoV have a proportion of VOC 202012/01 from samples collected in week 53, 2020 (2.84%) similar to that reported in week 45 in the UK (2.78%) (Figure 2 and Figure 5). Danish modelling studies indicate that VOC 202012/01 is expected to be the dominant circulating virus in mid-February 2021 [9]. Most VOC cases detected in Denmark were not travel-associated. Those patients infected with VOC 202012/01 and with a travel history reported having visited different countries, including the UK, Barbados, Lebanon, Switzerland, Tanzania (including Zanzibar) and the United Arab Emirates.

**Figure 5. Proportion of Danish SARS-CoV-2 sequences classified as VOC 202012/01 per week, and total sequences per week from Denmark (DK). GISAID EpiCoV, up to 12 January 2021**



Weeks 2 and 3 of 2021 are omitted due to very few sequences being available.

Source: GISAID EpiCov database. More detailed national analysis of sequences from Denmark is available from Statens Serum Institut [10].

In Ireland, an increasing proportion of VOC 202012/01, as indicated by S-gene target failure, has been reported since early December (when the proportion was <2%), and accounted for 46% of samples tested in week 1 of January 2021. It is noteworthy that all S-gene target failure cases sequenced to date (n=77) have been confirmed as VOC 202012/01 through Whole Genome Sequencing (WGS). VOC 202012/01 has been detected in all geographic regions and in all age groups.

In the Netherlands, random sampling of SARS-CoV-2 positive samples for sequencing indicated that 10% of the samples identified in week 1, 2021 were VOC 202012/01. However, VOC 202012/01 cases are not equally distributed in the Netherlands and Amsterdam and Rotterdam are hotspot areas.

In Portugal, as of 12 January, national authorities had reported 72 cases of VOC 202012/01 [11]. So far, the sampling strategy for sequencing has been systematic, focusing on sequencing samples collected for one week every month. Portugal has observed a notable increase in the number of all reported cases of COVID-19 in recent weeks. This increase has been attributed mainly to the relaxing of the NPIs during the end-of-year festive season but also, to a lesser extent, to the spread of the VOC 202012/01 in some regions of the country.

In Belgium, as of 14 January, media reported a total of 68 VOC 202012/01 cases isolated by the university laboratories of Leuven (46 cases), Antwerp (18), and Ghent (4) [12]. The cases in Antwerp were first detected by PCR (S-gene target failure) and belonged to eight clusters, five of which had a link to travellers from various countries (Lebanon, Switzerland, United Kingdom and Dubai). VOC 202012/01 has also been found in association with an outbreak in a home for the elderly, as reported by the media on 17 January 2021 [13].

No other EU/EEA Member States have reported sequence data to an extent where a quantitative assessment of the variant prevalence in the local population can be made. A large number have reported travel-related VOC 202012/01 associated with recent travel to the UK, but also to a number of other countries including Czechia, Poland and Sweden.

In Israel, national authorities are reporting widespread transmission of VOC 202012/01.

## Detection of the variant 501Y.V2

As of 14 January 2021, a total of 1 296 806 confirmed COVID-19 cases, including 35 352 deaths, had been reported in South Africa [14,15]. The country is in its second SARS-CoV-2 epidemic wave [14,16].

On 18 December 2020, the South African government reported the emergence and rapid increase of a new variant designated 501Y.V2. The earliest detection has been traced back to October 2020 [17]. As of 13 January 2021, 349 cases 501Y.V2 had been confirmed in South Africa, but this number is believed to be greatly underestimated as only a small fraction of samples from confirmed COVID-19 cases have been sequenced.

Since its identification and as of 19 January 2021, according to media and official sources, approximately 570 501Y.V2 cases have been identified in 23 countries.

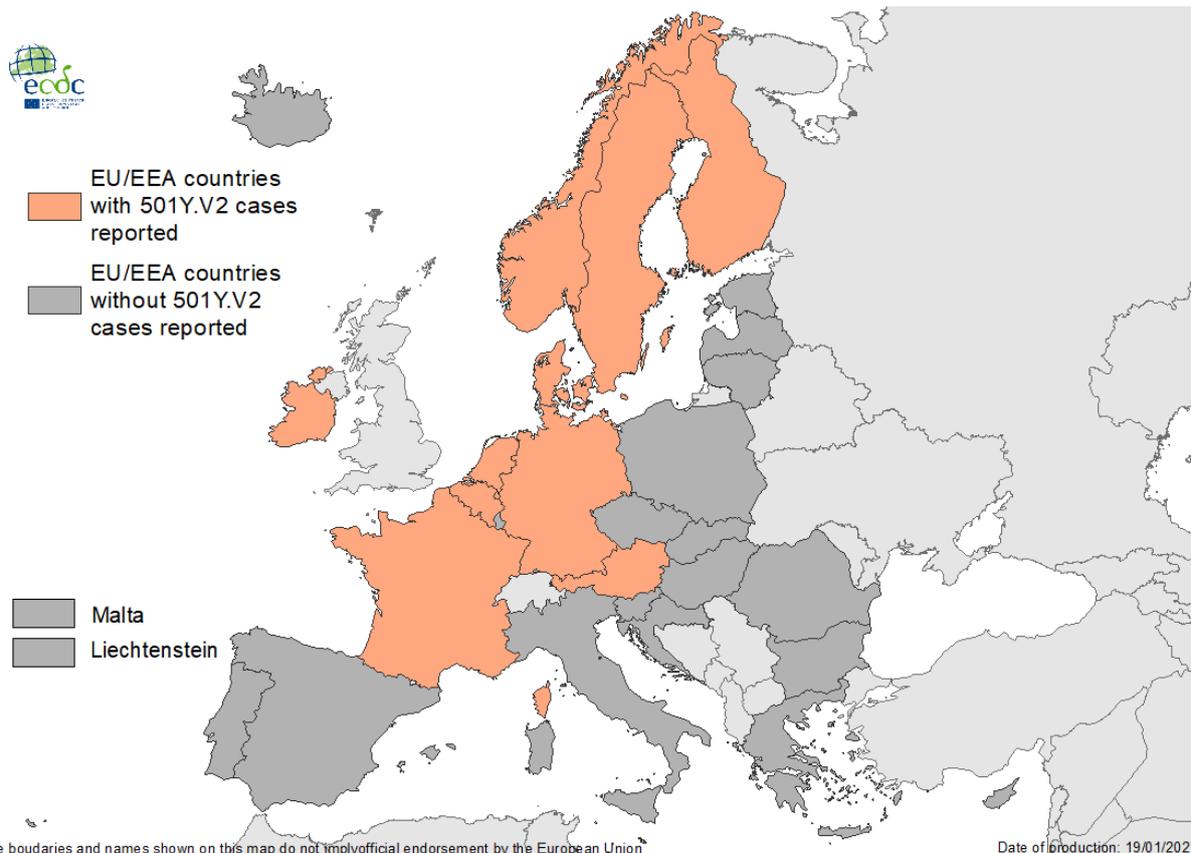
In the EU/EEA, 27 cases have been identified in 10 countries: Germany (6), France (5), Belgium (4), Ireland (3), the Netherlands (3), Denmark (1), Finland (2), Austria (1), Norway (1) and Sweden (1) (Figure 6).

Outside the EU/EEA, approximately 524 cases have been identified in 13 countries: South Africa (447), United Kingdom (54), Australia (6), Botswana (6), Canada (2), China (2), Switzerland (2), Brazil (1), Japan (1), South Korea (1) and Taiwan (1) and Zambia (1) (Figure 7).

Public health authorities are reporting clusters of 501Y.V2 cases in several regions of France. The initial cases in the cluster were a group of travellers returning from Mozambique in late December 2020 after participating in a religious gathering. Five travellers tested positive for SARS-CoV-2 upon return. Samples from two of the travellers were sequenced and found to be 501Y.V2. The follow-up investigation identified 29 confirmed cases distributed in four sub-clusters. The sub-clusters include cases in several French regions, with cases belonging to a number of households, including children attending schools. At least one patient from of this cluster has been admitted to an intensive care unit (ICU).

The majority of the remaining 501Y.V2 cases detected in the EU/EEA are travel-related, but not all have a travel history to South Africa. In addition, 501Y.V2 clusters or cases without a travel-history to South Africa are under investigation in Israel and the United Kingdom.

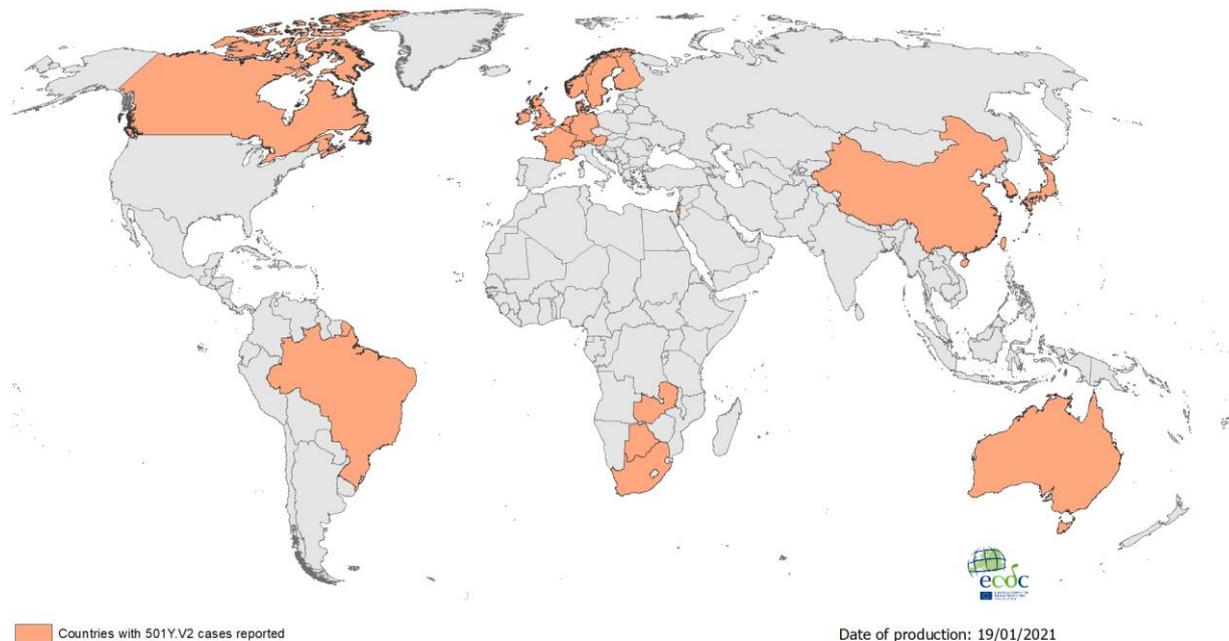
**Figure 6. Countries reporting cases of 501Y.V2 in the EU/EEA, as of 19 January 2021**



The boundaries and names shown on this map do not imply official endorsement by the European Union

Date of production: 19/01/2021

*Note: EU/EEA countries with 501Y.V2 cases on the map may not represent the full geographical extent of the variant spread in the EU/EEA.*

**Figure 7. Countries reporting cases of 501Y.V2 worldwide, as of 19 January 2021**

## New SARS-CoV-2 variant P.1

On 10 January 2021, Japan reported four cases of COVID-19 associated with a novel variant of SARS-CoV-2 in returning travellers from Brazil [18,19]. On 12 January 2021, a preprint article was published describing a variant detected in Manaus, Brazil, identical to the one detected in Japan [20]. The variant seems to have spread rapidly in Manaus, with 13 out of 31 genomes generated from 37 samples collected from patients seeking private healthcare in mid/late-December being identified as this variant. Manaus is currently experiencing an upsurge in COVID-19 cases, with significant pressure on the healthcare system. In spring 2020, Manaus experienced a large outbreak of COVID-19, with subsequent high levels of seropositivity being reported in the population.

On 18 January 2021, South Korea reported one case of variant P.1 in a returning traveller from Brazil [2]. Very little information is currently available about the epidemiology of this variant and ECDC's Epidemic Intelligence is monitoring the situation and also checking global sequence databases.

No EU/EEA countries have reported identifying this variant as of 19 January 2021.

## Overall COVID-19 epidemiological situation in the EU/EEA - data from The European Surveillance System

Detailed epidemiological information on laboratory-confirmed cases reported to The European Surveillance System (TESSy) is published in [ECDC's weekly COVID-19 surveillance report](#) [21] and the overview of the epidemiological situation in relation to the COVID-19 pandemic by country is also published in [ECDC's weekly COVID-19 country overview](#) [22].

### Trends in reported cases and testing

In ECDC's weekly surveillance report, by the end of week 1 (Sunday 10 January 2021), increases in notification rates of COVID-19 cases had been observed in 13 countries (Cyprus, Czechia, France, Hungary, Ireland, Italy, Latvia, Malta, Portugal, Romania, Slovakia, Slovenia and Spain). Case rates among older age groups had increased in 11 countries (Annex 2, Figure 1).

Among 23 countries in which weekly test positivity was high (at least 3%), seven countries (France, Germany, Ireland, Malta, the Netherlands, Portugal and Spain) had observed an increase in test positivity compared with the previous week, while the rate remained stable or had decreased in 16 countries (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Estonia, Hungary, Italy, Latvia, Lithuania, Poland, Romania,, Slovakia, Slovenia and Sweden) [23].

## Hospitalisation and ICU

For week 1, hospital and/or ICU occupancy and/or new admissions due to COVID-19 were high (at least 25% of the peak level during the pandemic) or had increased against the previous week in 29 countries (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden [23]).

## Mortality

Among 27 countries with high 14-day COVID-19 death rates (at least 10 per million), increases were observed in ten (Czechia, Denmark, Germany, Ireland, Latvia, Liechtenstein, the Netherlands, Portugal, Slovakia and Spain).

For week 1/2021, all-cause excess mortality data reported from participating European countries to the EuroMOMO network identified a substantial increase in excess mortality, mainly affecting those aged 45 years and above [24].

## Disease and virus background

For additional information on the latest scientific evidence relating to COVID-19, SARS-CoV-2, virus transmission, diagnostic testing, infection, clinical characteristics, risk factors and risk groups, immunity, and vaccines and treatment please visit ECDC's website: <https://www.ecdc.europa.eu/en/covid-19/latest-evidence>.

## Characteristics of the new variants

### VOC 202012/01

VOC 202012/01 was first identified in the UK. It belongs to Nextstrain clade 20B [25,26], GISAID clade GR [2,27] and lineage B.1.1.7, as assigned by Pangolin [28,29].

VOC 202012/01 is defined by multiple spike protein changes (deletion 69-70, deletion 144, amino acid change N501Y, A570D, D614G, P681H, T716I, S982A, D1118H) as well as by mutations in other genomic regions [30].

### Transmissibility

Several modelling studies corroborate the postulated increased transmissibility of VOC 202012/01 [31-33]. Vöhringer et al. reported that VOC 202012/01 had spread during the English lockdown in 87% of local authority areas with a lower degree of implemented NPIs, with an average  $R=1.25$  in contrast to other lineages, which had an average  $R=0.85$  [34]. Leung et al. used the combination of N501Y and  $\Delta 69/\Delta 70$  markers as surrogates of the VOC 202012/01 to estimate its  $R_0$  between 22 September and 1 December 2020 in the UK. In line with previous modelling studies, the  $R_0$  for VOC-202012/01 was estimated as 75% more transmissible than other variants [35]. Davies et al. modelled data from three English regions to estimate that VOC 202012/01 is 56% more transmissible (95% credible interval (CrI): 50-74%) than previously identified SARS-CoV-2 variants [32]. Danish modelling studies performed in January 2021 estimated that VOC 202012/01 was 36% more transmissible than other variants [ECDC communication with Danish authorities].

### Severity

There is currently no indication that infections with VOC 202012/01 are associated with more severe clinical presentation than pre-existing strains. The above-mentioned studies found no evidence of greater or lesser severity of VOC 202012/1 compared to pre-existing strains [32]. However, the estimated increased transmissibility, similar in all age groups [31,36], results in a higher absolute number of infections and thus increases pro rata in severe cases when prevention measures are kept constant.

### Diagnostic assays

The S-gene deletion at genomic positions 21765-21770, corresponding to residues 69-70 in the spike protein in variant VOC 202012/01 and other variants carrying this mutation, such as mink-related variants from Denmark, may cause some RT-PCR assays targeting the S-gene to produce a negative result (S-gene target failure) [37]. The S-gene target failure is unlikely to cause an overall false-negative result for SARS-CoV-2 as the S-gene is generally not used by itself for detection of the virus.

Five rapid antigen detection tests validated by the UK, all targeting the nucleocapsid protein which has two amino acid changes for VOC 202012/01 (D3L and amino acid change S235F), still meet minimum performance criteria for this variant [38].

### Immunity, reinfection, vaccination

The Public Health England Technical Briefing 4, on the investigation of VOC 202012/01, published on 15 January 2021, indicates consistent evidence of cross-neutralising activity in convalescent sera [39]. Sera from patients infected with non-variant virus show neutralising activity towards the variant virus, and vice versa. The same report also notes that there is antigenic difference (reduced cross-neutralisation activity) between the variant and other tested viruses, though the size of the difference still needs to be quantified and its significance investigated.

Studies are also ongoing with post-vaccination sera in the United Kingdom and elsewhere to determine if the VOC202012/01 poses a risk to vaccine match and vaccine effectiveness. However, there is no evidence of a significant difference in the risk of reinfection when comparing variant and non-variant viruses.

## 501Y.V2

Variant 501Y.V2, first identified in South Africa, belongs to Nextstrain clade 20C [25,26], GISAID clade GH [2,27], and lineage B.1.351 as assigned by Pangolin [28,29].

501Y.V2 is defined by multiple spike protein changes present in all viruses in the cluster (amino acid change D80A, D215G, E484K, N501Y and A701V), and more recently collected viruses have additional changes [30] (amino acid change L18F, R246I, K417N, and deletion 242-244) [40]. Three of the changes (amino acid change K417N, E484K, and N501Y) are located within the receptor-binding domain (RBD).

### *Transmissibility*

Preliminary results, using a mathematical model previously used to characterise the transmissibility of VOC 202012/01 [32] and simplified calibration, estimate that 501Y.V2 is 50% (95% CrI: 20-113%) more transmissible than previously circulating variants in South Africa [41]. As the 501Y.V2 variant carries spike protein changes that are associated with reduced neutralisation by antibodies [42], the authors tested the assumption of similar transmissibility to previous variants and estimated that, in this scenario, 501Y.V2 would need to evade 21% (95% CrI: 11-36%) of previously acquired SARS-CoV-2 immunity to account for the increased spread of the variant. A mix of these two scenarios is also possible, and there is no indication that one is more plausible than the other.

### *Severity, immunity, reinfection, vaccination*

There is currently substantial uncertainty as to whether the 501Y.V2 variant causes a change in disease severity [41]. The combination of amino acid changes in 501Y.V2 has been shown to confer complete resistance to neutralisation by several monoclonal antibodies, as well as reduced neutralisation, or complete resistance to neutralisation by convalescent plasma and sera in a preprint article [43]. These results raise some concerns about whether the variant can increase the risk of reinfection or vaccine breakthrough infections. No information is yet available as to whether the number of reinfections related to this variant is actually higher.

### *Diagnostic assays*

There is currently no known impact from the variant 501Y.V2 on diagnostic assays. The variant does not have the residue 69-70 deletion observed in VOC 202012/01, but does have another deletion at residues 242-244.

## P.1 variant

Variant P.1, described in Brazil, belongs to Nextstrain clade 20B [25,26], GISAID clade GR [2,27] and lineage P.1, as assigned by Pangolin (formerly P.1.1.28). This is sometimes incorrectly referred to as lineage B.1.1.248.

The variant is not closely related to VOC 202012/01 or 501Y.V2 and has 11 amino acid changes in the spike protein compared to its ancestral lineage B.1.1.28, three of which are located in the RBD. It has been assigned to the novel lineage P.1 as it is divergent from its ancestral lineage, and no other levels of classification are available in the naming scheme [28,29]. The full set of spike protein changes for the variant are amino acid change L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, H655Y, T1027I, and V1176F.

### *Transmissibility*

There is currently no microbiological or epidemiological evidence of any change in transmissibility of P.1, but the amino acid change N501Y, also present in VOC 202012/01 and 501Y.V2, indicates that increased transmissibility is plausible.

### *Severity, immunity, reinfection, vaccination and treatment*

Nothing is known yet about potential changes in infection severity in those infected with the P.1 variant. The presence of amino acid change E484K, also present in 501Y.V2, may indicate a reduction in neutralisation overall and by the anti-RBD monoclonal antibodies used in the assays [42,44,45]. As yet, there is no indication as to whether the number of reinfections related to this variant is higher.

### *Diagnostic assays*

There is no reported effect of the variant on diagnostic assays and the variant does not have any deletions in the S-gene, so it most likely does not give rise to S-gene target failure.

## ECDC risk assessment for the EU/EEA

This assessment is based on information available to ECDC at the time of publication and, unless otherwise stated, refers to the risk that existed at the time of writing. It follows ECDC's rapid risk assessment methodology, with relevant adaptations [46]. The overall risk is determined by a combination of the probability of an event occurring and its consequences (impact) for individuals or the population [46].

### Risk assessment question - What is the risk associated with the introduction and community spread of variants of concern in the EU/EEA?

The risk associated with the introduction and community spread of variants of concern is assessed as **high/very high**. This assessment is mainly based on information available for VOC 202012/01, as too little information is available as yet for 501Y.V2 and the P.1 variant. This assessment is based on the following factors:

The probability of introduction and community spread of variants of concern, and particularly SARS-CoV-2 VOC 202012/01, in the EU/EEA countries is assessed as **very high** for the reasons set out below.

- SARS-CoV-2 VOC 202012/01 has been circulating in the UK since at least 20 September 2020. Despite measures being in place throughout the country during the latter part of 2020, the variant has increased in the proportion of all sequenced viruses and has been a contributor to the overall increase in case notification.
- The transmissibility of VOC 202012/01 is estimated to be significantly higher than that of the previously circulating SARS-CoV-2 virus in the UK.
- As of 19 January 2021, cases of SARS-CoV-2 VOC 202012/01 have been reported from 60 countries worldwide, 23 of which are in the EU/EEA.
- Denmark, Ireland and the Netherlands are reporting significant community transmission of this variant in their countries, with most of the recent VOC 202012/01 cases not being travel-associated. In addition to the EU, Israel is also reporting widespread transmission of VOC 202012/01.
- There is known under-ascertainment of SARS-CoV-2 infection generally, given that many individuals, and particularly those with a milder course of infection or no symptoms, are not tested. Sequencing of samples from confirmed SARS-CoV-2 cases is generally only performed for a very small proportion of cases in most EU/EEA countries. Therefore, it is highly likely that there is under-ascertainment of the true number of VOC 202012/01 cases.
- The lag time of increase for each region/country depends on the extent to which the new variant has been introduced into their territory and the opportunity for it to spread among more individuals. This, in turn, depends on the degree of NPIs implemented (e.g. physical distancing measures) in the affected area and compliance with those NPIs. Such an increase can occur rapidly, within a matter of weeks.
- 501Y.V2 has been circulating in South Africa since August 2020 and has increased as the proportion of all sequenced virus samples. It has been contributing to the overall increase in case notifications in local areas and in the country as a whole.
- As with the VOC 202012/01, the transmissibility of 501Y.V2 is preliminarily estimated to be significantly higher than that of the SARS-CoV-2 virus which was previously circulating.
- The number of 501Y.V2 cases reported outside South Africa is increasing. In the EU/EEA, 501Y.V2 has been reported by 10 countries. A cluster of 501Y.V2 has been found in France, with 29 cases identified so far, only five of which are travel-associated (returning from Mozambique). Most of the other 501Y.V2 cases detected in the EU/EEA are travel-related, even though not all are from South Africa, with imported cases reported from other African and Asian countries as well. 501Y.V2 clusters or cases without a travel history to South Africa are under investigation in Israel and the United Kingdom.
- As for VOC 202012/01, the under-ascertainment of SARS-CoV-2 infections in general, and the very small proportion of cases undergoing sequencing in most EU/EEA countries, indicate the likelihood of a gross under-ascertainment of the true number of 501Y.V2 and P.1 cases.
- The P.1 variant has been circulating in Brazil. It has also been identified in Japan and South Korea in travellers from Brazil (mostly from the Amazonas State). The Amazonas capital, Manaus, is currently experiencing a large increase in COVID-19 reported cases, which has placed the local healthcare system under great strain.
- No data are available yet on the transmissibility of the P.1 variant. Information as to whether the current increase in cases in Manaus is associated with the P.1 variant is not available. It should be noted that Manaus has experienced a large wave of infections, and associated pressure on healthcare provision. Already in spring 2020, this resulted in high levels of population immunity being reported, even though the variant P1 was still unknown at that time.
- The P.1 variant has not been identified in the EU/EEA so far.

The impact of introduction and community spread of variants of concern, and particularly SARS-CoV-2 VOC 202012/01, in the EU/EEA countries is assessed as **high** for the reasons set out below.

- Increased transmission rates place greater pressure on clinical and diagnostic laboratories to perform detection and characterisation of viruses and increase the demand for laboratory reagents and consumables.

- Increased transmission rates associated with variants of concern also mean that, even in the absence of a higher severity of the disease, the larger number of COVID-19 cases, and consequently the higher number of hospitalisations and ICU admissions is likely to increase pressure on the healthcare systems in countries where the new variant becomes established.
- Due to the high transmission rates observed in recent weeks, to which VOC 202012/01 has contributed, the UK has recently experienced a surge in demand for healthcare services, with a high number of reported hospitalisations and ICU admissions. The number of daily reported deaths in January has been the highest since the beginning of the pandemic. England and the three devolved administrations have implemented stricter NPIs to reduce pressure on the health service.
- As in the UK, in Ireland, the demand for healthcare services has been very high since late December and the circulation of VOC 202012/01 might have contributed to this. Ireland has escalated NPIs to reduce pressure on healthcare services.
- Denmark, where VOC 202012/01 is spreading, has implemented stricter NPIs since mid-December 2020 to be better prepared for an anticipated surge in cases in February 2021 due to VOC 202012/01.
- As of week 1, 2021, hospital and/or ICU occupancy and/or new admissions due to COVID-19 were high or had increased against the previous week in all EU/EEA countries, indicating that many health systems are already experiencing high pressure related to COVID-19. This may not necessarily be associated with the circulation of VOC 202012/01, but could be exacerbated by any increase in the circulation of these new, more transmissible variants.
- To date, no increased incidence of reinfections has been reported with VOC 202012/01 in those previously infected with non-variant viruses. Studies addressing reinfections are urgently needed.
- There is currently no evidence that infections with VOC 202012/01 or with 501Y.V2 are associated with a more severe clinical presentation or that they disproportionately affect certain age groups more than pre-existing infections. Studies of severity in individuals infected with variants of concern are urgently needed.
- Available evidence from studies on convalescent sera performed in the UK show cross-neutralising activity, with sera from patients infected with non-variant virus showing neutralising activity towards VOC 202012/01, and vice versa.
- Although results from studies on post-vaccination sera are not yet available, current COVID-19 vaccines are expected to offer protection against infection with VOC 202012/01, as is the case for infection with the non-variant virus [47].
- Early results on 501Y.V2 resistance or reduced neutralisation by several monoclonal antibodies, convalescent plasma and sera is of concern, as the variant could increase the risk of reinfection or vaccine breakthrough infections [43]. No information on neutralising antibodies is available yet for the P.1 variant but reported mutations in the spike region may also have a potential impact on vaccine effectiveness. This assessment will be updated as more data become available.
- Based on the above, the introduction and community spread of SARS-CoV-2 variants of concern may lead to an increased number of infections, hospitalisations and deaths, particularly for those in older age groups or with comorbidities. To reduce transmission and achieve the same level of control of the outbreak, stricter implementation and compliance with NPIs will probably be required.

In summary, the probability of introduction, displacement of current circulating viruses and community spread of SARS-CoV-2 variants of concern in the EU/EEA is currently assessed as **very high**, and its impact as **high**. The overall risk associated with the introduction and community spread of SARS-CoV-2 variants of concern in the EU/EEA is therefore assessed as **high/very high**.

## Options for response

Based on available data, countries in the EU/EEA should expect increased numbers of COVID-19 cases due to the gradual spread and possible dominance of the variants with increased transmissibility. The rate and scale of this increase will probably depend on the level of application of NPIs and compliance with them.

As such, the key message is to prepare for a rapid escalation of the stringency of response measures in the coming weeks to safeguard healthcare capacity and to accelerate vaccination campaigns.

## Surveillance, testing and detection of the emerging variants

Detection of the extent to which variants of SARS-CoV-2 are circulating requires systematic sequencing of a representative or random selection of detected viruses, which should be coordinated regionally and nationally. Laboratories should consider implementing pre-screening RT-PCR approaches to detect N501Y or S-gene target failure (deletion 69-70) variant viruses. Real-time surveillance of variant viruses is the key to developing public health response measures to reduce the impact of potential increased transmission in the population. All laboratories should be requested to report their results to the national public health institute that coordinates the collection of information. National public health authorities should notify cases of the variants of concern through the Early Warning and Response System (EWRS), and TESSy for case-based surveillance and aggregate reporting (which has been adapted for this purpose).

To be able to confirm infection with a specific variant, sequencing of the whole SARS-CoV-2 genome, or at least the S-gene for the current variants, is required. However, sequencing generally takes longer than virus detection methods, and the sequencing capacity is currently limited in most EU/EEA Member States; as already discussed in the previous version of this risk assessment [33].

For the VOC 202012/01, a negative S-gene result in multiplex RT-PCR assays, with positive results for the other targets, has been used as an indicator or pre-screening method to identify the variant. However, it should be noted that this target failure is not exclusive to VOC 202012/01, and confirmation using sequencing is always recommended. The S-gene target failure does not occur for 501Y.V2 and most probably not for lineage P.1. At present, no specific assays are available for targeted PCR assays to directly confirm VOC 202012/01 or 501Y.V2. However, several assays are available that can pre-screen to select samples for sequencing [37,48,49]. Increasing the numbers of sequenced samples pre-screened by S-gene target failure can be considered to assess the regional correlation between S-gene target failure and VOC 202012/01 as this varies with the regionally circulating variants [50]. If the correlation is very high, S-gene target failure can be used to approximate the frequency of VOC 202012/01.

Guidance on how to calculate the minimum number of viruses to be sequenced can be found in the first update of ECDC's technical guidance [Sequencing of SARS-CoV-2](#) [51]. A minimum ability to roughly quantify the proportion of a variant present at a prevalence of 2.5% of the total circulating variants is recommended. This requires each country to sequence at least around 500 randomly selected samples each week. According to scenarios developed by Denmark, if the variant is present at levels above 2.5%, it will probably impact total case numbers in the coming weeks [9]. In addition, sequencing of samples from large outbreaks and samples connected to travellers (either from point of entry screening or outbreaks involving a traveller) should be prioritised. Finally, sequencing should be prioritised for individuals who present with a 'breakthrough infection' identified >14 days after receiving the first dose of COVID-19 vaccine (see section on Vaccination).

Viral isolation of variants of SARS-CoV-2 should be carried out in P3 (Biosafety level (BSL) 3) laboratories to prevent the accidental dissemination of a variant through laboratory exposure [52].

For Member States with limited capacity to perform sequencing: abrupt changes in transmission rates or disease severity should be monitored. Data analysis and assessment of the local, regional and national situation should be performed to identify areas with a rapidly changing epidemiology.

The monitoring of environmental samples from sewage, mainly in urban areas, is also a method used by some Member States as an early warning system to alert for sudden increases in transmission and imminent outbreaks. However, these systems have not been standardised for SARS-CoV-2 yet and the detection of variants through sewage samples would still require the use of sequencing [53].

In general, laboratory preparedness should be among the current high priorities, and laboratories should:

- consider implementing diagnostic pre-screening for variants of concern (e.g. N501Y and deletion 69-70);
- ensure human and material resources are available to manage an increasing number of requests for detection and characterisation of SARS-CoV-2 samples;
- increase sequencing capacity by making use of all possible sequencing capacity in the Member States from clinical, diagnostic, academic and commercial laboratories, or requesting assistance from ECDC.

It is expected that a global framework will be established by WHO to assess the epidemiological and phenotypic properties of circulating SARS-CoV-2 variant viruses and their impact on transmissibility, disease severity, diagnostics and pharmaceutical interventions [54]. Meanwhile, in collaboration with the European Commission and WHO's Regional Office for Europe, ECDC will develop draft triggers for the investigations to be conducted on newly identified variants. This draft EU framework will then be aligned with the global framework.

## Non-pharmaceutical interventions

### Community measures

Efficient implementation of non-pharmaceutical interventions (NPIs) in response to the epidemiological situation remains essential for the continuing response to emerging and regularly circulating SARS-CoV-2 variants, until and unless vaccination has been shown to fully mitigate the impact of the pandemic on the population and healthcare services.

In areas where VOC 202012/01 is the dominant variant in circulation, stringent implementation of NPIs is necessary to reduce transmission and safeguard the healthcare system. Higher transmissibility implies that the effectiveness of several individual NPIs (e.g. physical distancing or the use of face masks) may be reduced and that more intensive layering of NPIs will be needed to achieve similar results [10]. Early implementation of NPIs, by even a few weeks, can prevent widespread SARS-CoV-2 circulation and contribute to the prevention of hospitalisations and fatalities, as shown by several studies [55,56]. For an analysis and available evidence on the NPIs used to respond to the COVID-19 pandemic please refer to ECDC's technical document 'Guidelines for the implementation of non-pharmaceutical interventions against COVID-19' [57].

More stringent implementation of NPIs may include a mandate to ensure that a larger proportion of the population works from home; limiting further or cancelling mass gathering events; implementing social bubbles; controlling or closing high-risk businesses (e.g. bars and restaurants); implementing curfews, etc. To achieve this, Member States need to accelerate and improve risk communication strategies to overcome the understandable 'COVID-19 fatigue' effect. Member States should also explore ways in which to support vulnerable and underprivileged populations to enable them to comply with physical distancing measures.

See Annex 1 for the measures implemented already in EU/EEA countries with widespread circulation of the VOC 202012/01.

## Shielding medically and socially vulnerable populations

Strategies to protect persons from medically and socially vulnerable populations, in particular residents of long-term care facilities (LTCFs) and other populations living in confined structures (e.g. prisons, migrant and reception centres) should be maintained and strengthened [58]. This includes helping people to avoid crowded places, both indoors and outdoors, and providing infection prevention and control support, logistic and mental health support, and access to testing. However, medically and socially vulnerable people's need for social interaction should be taken into account.

## Considerations for school settings

Incidence of COVID-19 in school settings appears to be mainly affected by levels of community transmission [59]. Widespread transmission of more highly transmissible variants of SARS-CoV-2 would therefore increase the likelihood that COVID-19 cases appear in school settings, even if these variants are not more transmissible among the young. As ECDC and WHO have noted, there are many profound negative impacts of school closures and it is therefore recommended that school closures are a measure of last resort, implemented as an additional, time-limited layer where other NPIs have not been able to control local transmission [59,60] and where school closure will lead to further reductions in the effective reproductive number (R).

Although transmission of VOC 202012/01 is similar in different age groups, increased community circulation may lead to the need for reactive school closures, either in response to school-specific outbreaks or to alleviate pressure on community transmission and the healthcare system [32]. It is generally thought that school closures, if deemed necessary, should initially be arranged for children in the older age groups. An age-structured model from the Netherlands concluded that the biggest impact on community transmission was achieved by reducing contacts in secondary schools [61].

Prior to taking decisions to close schools, countries should carefully review the other NPI measures in place, while also strengthening in-school measures to reduce the risk of SARS-CoV-2 transmission in school settings [59]. A wide range of mitigation measures should be considered that minimise social mixing between school classes and adult staff, and these appear to be effective [59,62]. Contact tracing in school settings remains important, in particular for cases suspected to be infected with the virus variants (see below). Special considerations for contact tracing in school settings are outlined in ECDC's guidance on contact tracing and ECDC's technical report on COVID-19 and the role of school settings [59,63].

Decision-making surrounding school closures or re-openings should be accompanied by effective risk communication. In line with evidence on the importance of community engagement generally [64], the school community should be viewed as a partner and a resource in order to optimise the response. Moreover, schools are important venues for science education and learning about good hygiene practices, such as handwashing. Students can become effective advocates for disease prevention and control in their homes, the school and the community at large [65].

## Contact tracing for emerging variants

The emergence of variants highlights, yet again, the importance of strengthening contact tracing efforts. The overall performance of contact tracing, follow-up of contacts, and adherence to quarantine need to be reinforced, given that a proportion of all cases will be variants, even though they might not be identified as such.

Contact tracing of cases suspected to be infected with variants (e.g. confirmed COVID-19 case with S-gene deletion, or any case with an epidemiological link) should be prioritised and efforts made to trace and follow up both high-risk and low-risk exposure contacts in a timely manner and as completely as possible (as per Tables 1 and 2 in ECDC's contact tracing guidance document) [63].

For cases suspected to be infected with VOC, especially during the phase where the variant is not yet widely circulating, additional contact tracing actions could be considered to mitigate the spread of the new variants as far as possible. These actions are set out below.

- Retrospective or 'backward' contact tracing could be carried out to identify the possible source of infection. Further contact tracing should then be undertaken in relation to that source.
- In addition to testing high-risk exposure contacts when tracing (and low-risk contacts in some settings), as recommended in ECDC's contact tracing guidance document, low-risk exposure contacts could also be tested as soon as they are identified to allow for further contact tracing, given the increased transmissibility of VOC.

- ECDC guidance on contact tracing recommends that high-risk exposure contacts should quarantine for 14 days after last exposure to a case or that they can be released following a negative RT-PCR test on Day 10. Some residual risk of transmission remains with these strategies [66,67] and in order to increase the chance of containing the spread of the new variant, public health authorities could consider releasing high-risk exposure contacts only after a negative RT-PCR test taken on Day 14, which can be expected to reduce some of this risk [67]. To further mitigate the remaining residual risk, in the week after release from quarantine, contacts should also be reminded to strictly observe physical distancing measures at all times, wear a face mask, and isolate and report immediately if symptoms develop.
- To reduce spread from high-risk contacts who develop asymptomatic infection while in quarantine, household members of quarantined high-risk contacts should be advised to observe strict physical distance measures at all times, wear a face mask outside the home, and isolate and report immediately if symptoms develop.
- If a contact of a case suspected to be infected with a VOC has symptoms when they are identified or if they develop symptoms during follow-up, public health authorities should immediately start contact tracing of their contacts before the test result is confirmed.
- During communication with contacts, emphasise the importance of adhering to quarantine and explain that the variant is more transmissible so that they are aware of the public health importance of preventing the variant from becoming established.
- Consider sequencing at least a random number of RT-PCR positive contacts, to confirm the prevalence of variant viruses within the cluster or outbreak, and to closely follow the emergence of any variant.

Given that some contacts may already be infectious by the time the test result is obtained and the contacts traced, public health authorities can consider asking people when they take the test to inform their closest contacts straightaway to take extra precautions (physical distancing or wearing of face masks) while the result is being processed.

## Measures for travellers

The introduction of SARS-CoV-2 variants cannot be completely prevented through travel measures. However, a modelling study showed that slowing down the introduction of this pathogen could prevent the triggering of larger outbreaks in destinations where R is close to 1 [68,69]. Travel measures can only complement, and cannot replace the implementation of the necessary community measures (e.g. testing, contact tracing, isolation of cases and quarantining of their contacts). When defining travel measures and affected areas, policymakers should consider the under-ascertainment of SARS-CoV-2 infections in general and the limited availability of sequencing data in many countries, as well as substantial reporting delays [69]. Therefore, the expected impact of travel measures needs to be carefully weighed against the public health resources required to implement them and the expected impact on the local epidemiological situation. Travel measures should also take into account the evidence on the circulation of variants of concern in countries from which travellers are arriving.

In order to slow down the importation and spread of the new SARS-CoV-2 variants of concern, ECDC recommends that non-essential travel should be avoided. In addition to recommendations against non-essential travel, and restrictions on travel for those with active infection, measures such as testing and quarantining of travellers should be maintained, in particular for those coming from areas with higher incidence of the new variants. If sequencing is inadequate to exclude the possibility of a higher incidence of the new variants, as per ECDC guidance on genomic sequencing [51], proportionate travel measures should also be considered from areas which continue to have a high level of community transmission. Escalated measures for relevant groups of travellers that could be considered include:

- quarantining of travellers for 14 days (unless test is performed, see below);
- testing on arrival and on Days 7-10 during quarantine, in order to be released from quarantine if negative;
- enhanced contact tracing, as described in the relevant section above.

ECDC recommends the use of Passenger Location Forms (PLFs), preferably in digitalised form, including during transit through other airports on the way to the final destination.

There is currently insufficient evidence to exempt travellers with proof of vaccination from quarantine and/or testing, as there are still critical unknowns regarding the efficacy of vaccination in reducing transmission and limited availability of vaccines. Proof of vaccination should not cause international travellers to be exempt from complying with other travel risk reduction measures [54].

The relevance of these measures applies not only to international cross-border travel (irrespective of the form of conveyance), but also to countries where localised or regionalised emergence of variants of concern has been detected. Depending on the epidemiological situation, national authorities should also consider implementing similar measures at the sub-national level, to limit or delay spread and safeguard the health system in hard-to-reach geographical areas.

COVID-19 positive samples from travellers should be prioritised for sequencing, and enhanced contact tracing performed, as described in the section above.

Monitoring implementation of and compliance with these measures should be part of the response system. Any travel-related measure should be applicable to all travellers, irrespective of the means of transportation or their vaccination/immunisation status, at all points of entry.

## Vaccination

In the short-to-medium term the roll-out of vaccination will probably contribute to the response in terms of reducing the impact of the outbreak by protecting higher-risk groups from severe disease. However, in the short term the supply of vaccines is and will continue to be limited and available doses should be used optimally.

### Availability of COVID-19 vaccines

Two mRNA vaccines developed by BioNTech/Pfizer and Moderna have been authorised in the EU as of 19 January 2021 for protection against COVID-19. The two vaccines are currently being delivered to Member States and their use should be strongly encouraged in line with national recommendations [70,71]. No data are available on the interchangeability of the two mRNA vaccines or other COVID-19 vaccines. It is currently recommended that the same product should be used for both doses, but studies on the mixing of different vaccine types are planned to start soon to understand if this is an acceptable, or even advantageous approach. A third vaccine developer, AstraZeneca, has filed for EU authorisation and EMA has informed the public that an opinion on the marketing authorisation could be issued by 29 January 2021 [72]. All three vaccines are developed to trigger an immune response to the spike protein (the mRNA vaccines in the pre-fusion confirmation), according to the sequence from the Wuhan-1 SARS-CoV-2 virus strain published in January 2020. Therefore possible breakthrough infections following vaccination must be monitored.

### Monitoring breakthrough infections following vaccination, adjustment of vaccination schedules and possible update of vaccine contents due to SARS-CoV-2 variants in circulation

At this stage with new variants in circulation, it must be emphasised that breakthrough infections following vaccinations should be monitored in all Member States. Any such infections should be carefully investigated, including the sequencing of virus variant causing the breakthrough infection, and reported to public health and regulatory agencies to allow for an overview at country and EU-level. In addition, it should be noted that SARS-CoV-2 infections following dose one are expected in the first 14 days before an immune response has been mounted, so breakthrough infections occurring >14 days after vaccination should be investigated, prioritised for sequencing and then reported. For countries with electronic databases with only limited data lag, monitoring for breakthrough infections in real time through linkage of electronic immunisation registries with PCR or antigen testing results from electronic healthcare records is advantageous.

Options for the optimal use of a limited number of vaccine doses are being explored, including obtaining six doses from a five-dose vial for the BioNTech/Pfizer vaccine [73], in line with the updated Specific Product Characteristics. Another option is the modification of the immunisation schedule in order to provide the first dose of the vaccine to the largest number of individuals possible.

It is currently unknown if adjustments of vaccination schedules will be needed due to the virus variants. The first authorised COVID-19 vaccines are recommended for use in two-dose schedules. To allow for more individuals to be protected, the space between Dose 1 and 2 has been prolonged to up to 12 weeks in the United Kingdom [74]. Studies are ongoing to assess whether one or two doses are needed for protection against the non-variant viruses and the new variants. On 8 January 2021, WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recommended an interval of no longer than six weeks, unless careful monitoring of breakthrough infections was implemented [75]. However, in this situation, it is important to use the available vaccines in line with national recommendations to provide protection against the current circulating virus variants in the EU/EEA, since cross-protection is expected. However, the level of cross-protection could possibly vary for the different variants [31], particularly in the case of the 501Y.V2 variant. For this variant, two non-peer reviewed reports of resistance or reduced neutralisation by several monoclonal antibodies, convalescent plasma and sera give cause for concern as the variant could increase the risk of reinfection or vaccine breakthrough infections [43,76].

Assessment of neutralising antibodies (using both convalescent sera following natural infection, sera from vaccinated individuals and monoclonal antibodies) is ongoing for the identified variants. In addition, standardisation of assays is needed, assessing both B- and T-cell immunity following natural infection and vaccination with different vaccines using different SARS-CoV-2 variants. This standardisation has been initiated by the UK National Institute for Biological Standards and Control (NIBSC), Public Health England and the Coalition for Epidemic Preparedness Innovations (CEPI). Development of a framework for overall assessment of new variants hosted by WHO has also been proposed and is currently being built and this will necessitate collaboration between public health bodies and regulators worldwide.

As mentioned above, the two mRNA vaccines are based on the initial Wuhan-1 virus sequence of the spike protein. Both BioNTech/Pfizer and Moderna have publicly stated in media [77,78] that, if necessary, it will be possible to update their vaccines with a new variant. BioNTech indicated it could do this within six weeks. However, this does not take into account production time, which would probably need to be added to this timeline. Manufacturing capacity is currently already being increased in the EU due to the urgent need for further doses both within the EU and elsewhere. EMA is currently exploring options for the timely approval of a vaccine strain update, should this be warranted.

## Accelerating vaccination campaigns

Member States should accelerate vaccination roll-out programmes in order to protect those most at risk from severe disease, and reduce the burden on health systems. When more vaccine doses become available, possible options for acceleration of vaccination campaigns may include:

- increasing the number of vaccination centres;
- increasing the number of vaccinating staff (e.g. primary care staff, retired healthcare workers, etc.);
- reviewing the prioritisation [79] of risk groups to be vaccinated to ensure that those at highest risk of hospitalisation and death are rapidly protected, depending on vaccine availability;
- continuously monitoring vaccination deployments and rapidly addressing shortcomings;
- deploying the vaccine as a priority to severely affected regions.

## Vaccine effectiveness studies

In order to investigate variant-specific vaccine effectiveness, studies will need to ensure that the diagnostics used will detect all variants of SARS-CoV-2 that are in circulation, with very high sensitivity and specificity. As described above, during vaccine roll-out surveillance and sequencing needs to continue to provide vaccine product-specific effectiveness results and also variant-specific vaccine effectiveness results.

## Hospital and healthcare preparedness

In countries and/or regions where COVID-19 incidence is increasing and/or where the new variants of concern have been identified and a scenario foreseen (Scenarios 3 and 4, as defined in ECDC guidance) where sustained community transmission is established, it is crucial that hospitals and healthcare settings are prepared [80,81].

Hospital preparedness remains an absolute priority at this time, and should include:

- activation of response plans to manage increasing numbers of COVID-19 cases, as well as to prevent and control any nosocomial transmission;
- activation of surge capacity plans to address the expected high demand for care. This entails space, equipment, oxygen and oxygen delivery systems, but most importantly, training of existing staff and surge capacity staff in the clinical management of COVID-19 cases. Involvement of volunteers and transfer staff should also be foreseen.

In addition, hospitals and healthcare settings in areas with a high incidence of COVID-19 should:

- Discourage symptomatic patients from presenting to healthcare facilities without prior instructions, with the exception of medical emergencies.
- Ensure that care for other diseases conditions is maintained to the extent possible, with strict infection prevention and control precautions to avoid nosocomial transmission of COVID-19.
- Ensure that mild, sub-intensive and intensive care, including access to extracorporeal membrane oxygenation (ECMO) for critical patients, is coordinated in designated treatment facilities. This implies the activation of hospital contingency plans to be able to cancel elective diagnostic and operative procedures and re-assign human resources.
- Use temporary treatment facilities as an option for mild cases, or alternatively, provide advice and instructions on self-isolation until symptoms improve.
- Limit access to hospitals for family and friends of admitted patients. Consider only allowing visits with appropriate protection for palliative care or end-of-life patients.
- Decrease the regular administrative workload for healthcare workers. For example, arranging for provision of prescriptions or other certificates electronically or by phone can free up resources.
- Prepare or adapt business continuity plans for healthcare facilities in accordance with the latest public health risk assessment and guidance from national, regional or local health authorities to ensure continuity of essential services. Involvement of volunteers and transfer staff should be foreseen.

Further support on hospital and healthcare setting preparedness is available in ECDC's 'Guidance for health system contingency planning during widespread transmission of SARS-CoV-2 with high impact on health services' and 'Checklist for hospitals preparing for the reception and care of coronavirus 2019 (COVID-19) patients' [80,81].

## Knowledge gaps

There are currently many uncertainties and knowledge gaps related to the impact of the VOC 202012/01 or other variants (i.e. 501Y.V2 and lineage P.1), including the extent of geographical spread across the EU/EEA, affected age-groups, transmissibility and severity. The overall impact of the disease epidemiology at population level, including reinfection and effect on vaccination, and the longer term evolution of the variants and emergence of new variants is also unknown. Epidemiological and phylodynamic analyses, together with antigenic and genetic characterisation analyses, are urgently needed on an ongoing basis.

## Limitations

- This assessment is based on data available to ECDC as of 19 January 2021. There are still limited neutralisation assay data for the variants of concern.
- Sequence data generation and analysis both require time to be performed. This, together with the time required to upload to the GISAID database and share publicly, means that there may be a substantial lag in the data available, making it difficult to fully assess the occurrence and/or spread of these variants.
- The epidemiological data used in this assessment are dependent on availability from Member States through surveillance reporting or publicly available websites. The data are also dependent on local testing strategies and local surveillance systems. It is also important to consider the lag time between infection, symptoms, diagnosis, case notification, death and death notification.
- The effects and impact of lifting or imposing response measures may take weeks to be reflected in the population's disease rates. Assessing the impact of response measures is complex as many countries have lifted or relaxed multiple measures simultaneously at different times since the beginning of the pandemic.
- Changes in individual behaviour, compliance with measures, and cultural, societal, and economic factors all play a role in the dynamics of disease transmission.
- The assessment of the epidemiological situation and the effectiveness of the NPIs should therefore be interpreted with caution. Moreover, such assessment requires careful consideration of the national and subnational contexts.

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## Disclaimer

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# Annex 1

The sections below present short narratives and figures by country of interest for a set of key epidemiological indicators made available through national data portals and TESSy, together with key NPIs on physical distancing, such as stay at home order/recommendations at national and regional levels. Detailed information on NPIs is available weekly in the [ECDC Weekly COVID-19 country overview](#).

## Denmark

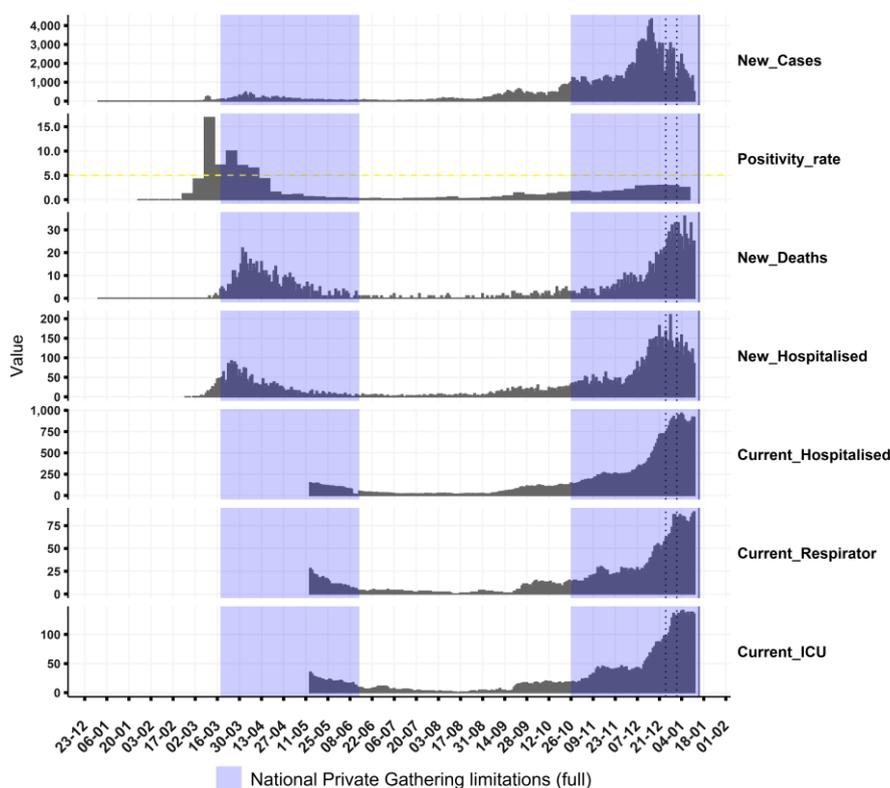
### Recent NPIs

On 15 December 2020, Danish authorities announced a set of physical distancing measures to be implemented at national level, including distance learning for school students from the fifth grade, recommendation of on-site work for critical function workers only and teleworking being encouraged for all other workers. Measures also included the closure of restaurants and other food establishments, venues for indoor sport and leisure activities, and the indoor areas of cultural institutions [82]. In addition, on 21 December 2020, it was announced that liberal service professions where physical distancing could not be ensured should be avoided and, on 25 December 2020, all department stores were closed [83]. Recommendations on limiting social contacts and assembly bans remained in place: ban on gatherings >10 people, recommendation for ≤10 people in private places, and ≤10 social contacts including New Year’s Eve [84]. On 21 December 2020, a specific recommendation for travellers was implemented encouraging self-isolation upon arrival from the UK [85]. On 29 December 2020, the above measures were extended until 17 January 2021. On 6 January 2021, the threshold for social bubble and private gathering recommendations was reduced to ≤5 people, as well as the public gathering threshold (lowered from 10 to 5 people) [86].

### Recent epidemic trend

The number of cases peaked between 14 and 18 December 2020, and a new peak of hospitalised cases followed later between 20 and 29 December 2020.

**Figure 1. Multiple daily epidemiological indicators of interest in Denmark as of 15 January 2021, and key non-pharmaceutical interventions**



**Sources:** Epidemiological daily indicators are retrieved from the data portal on epidemic trend (*Coronatal and monitoring*) [87]. Epidemiological data extracted on 15 January with latest data point on 13 Jan 2020. The source of weekly positive rate time series is reproduced based on ECDC’s *Data on testing for COVID-19 by week* as of 14 January 2020. Horizontal yellow dotted line at 5%. The vertical dotted lines represent the bank holidays (25 December 2020 and 1 January 2021) during the end-of-year festive season.

## Ireland

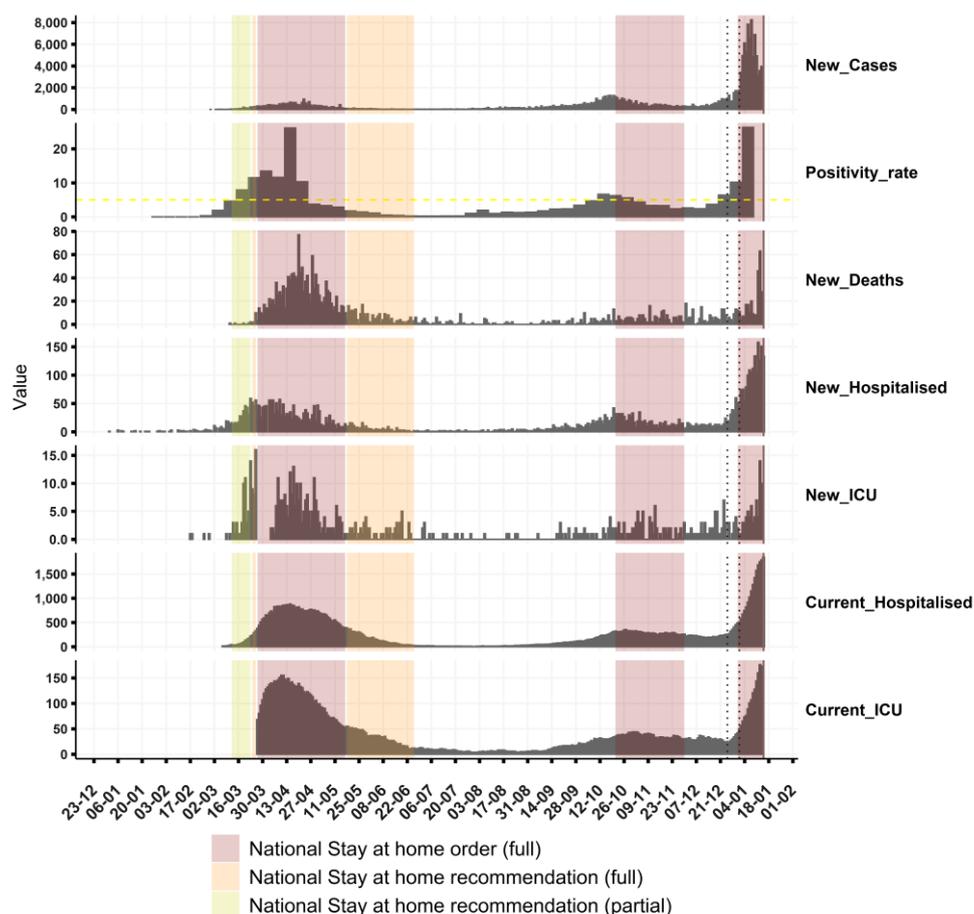
### Recent NPIs

In response to the second epidemic wave in autumn 2020, a set of NPIs were implemented nationwide in early October. These included closure of schools, closure of restaurants and cafes (except for take away), closure of pubs and entertainment venues, limitation of private gatherings to six people, cancellation of indoor gatherings, and limitation of outdoor gatherings to 15 people [88,89]. On 21 October 2020, the Irish authorities implemented national stay-at-home orders for a period of six weeks (Figure 2) [89]. On 1 December 2020, due to the improvement of epidemic trends, the Irish authorities relaxed restrictions for December and the end-of-year festivities, keeping the general principle of limited social bubbles and restrictions on the size of private gatherings [90]. On 31 December 2020, in response to a rapid increase in the number of new COVID-19 cases, new national stay-at-home orders were implemented [91,92].

### Recent epidemic trend

The number of new cases peaked on 8 January 2021 followed by a peak in new hospitalised cases on 12 January 2020, around 15 days after enforcement of NPIs. The early changes in outbreak dynamic are encouraging and need to be followed up in order to confirm that they are sustainable.

**Figure 2. Multiple daily epidemiological indicators of interest in Ireland as of 15 January 2021, and key non-pharmaceutical interventions**



**Sources:** Epidemiological daily indicators are retrieved from [Ireland's open data portal](#) and TESSy for new ICU/hospitalised cases in February and March 2020. The source of weekly positive rate time series is reproduced based on ECDC's [Data on testing for COVID-19 by week](#) as of 14 January 2020. Horizontal yellow dotted line at 5%. New ICU data series is incomplete for March 2021. The vertical dotted lines represent the bank holidays (25 December 2020 and 1 January 2021) during the end-of-year festive season.

## United Kingdom

### Recent NPIs

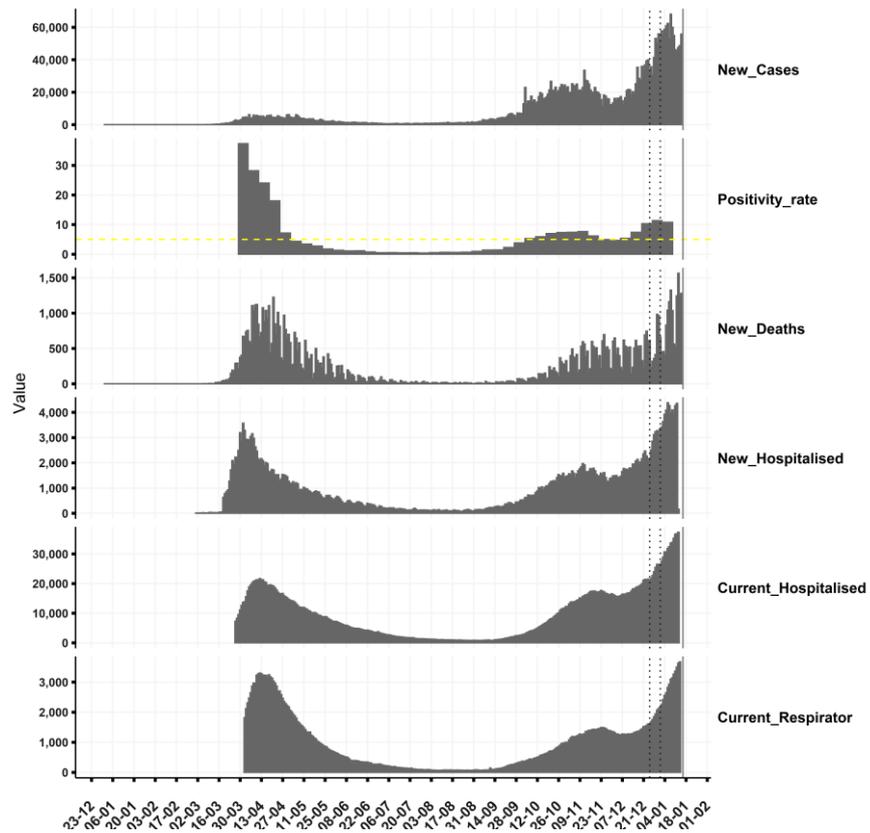
After the summer period, a second wave of the COVID pandemic occurred in the UK. The authorities in England and the three devolved administrations forming the UK then progressively tightened NPIs to respond to the new increase in COVID-19 cases.

- On 12 October 2020, England introduced a three-tier legal framework allowing local measures to be applied in different areas from the second half of October 2020. A four-week national lockdown started on 5 November 2020 without closure of educational institutions [93]. On 2 December 2020, a new regulation allowed for a relaxation for the month of December and the end-of-year festivities period [94]. On 5 January, stay-at-home orders were implemented [95].
- In Wales, the first local lockdowns were progressively implemented in several towns during September and October 2020. The Welsh authorities progressively enhanced NPIs until a short but strict national lockdown (so-called 'firebreak' lockdown) was implemented from 23 October to 8 November 2020. Stay-at-home orders were implemented starting on 20 December 2020 [96].
- New measures on physical distancing and face mask wearing were implemented in Scotland during the first half of October [97,98]. On 23 October 2020, a new five-level strategic framework came into force and NPIs were implemented at regional level within Scotland in November 2020. On 23 November 2020, Scottish authorities proposed a partial relaxation of the response measures in accordance with the local evolution of the key epidemiological parameters [99]. On 5 January 2021, stay-at-home orders were implemented in response to the deteriorating epidemiological situation [100].
- In Northern Ireland, the government introduced stay-at-home recommendations from 10 to 21 September 2020, then transitioning to a set of NPIs during autumn and for the end-of-year festivities [101]. On 8 January 2021, in response to a rapidly deteriorating epidemiological situation, a stay-at-home order was implemented [102].

### Recent epidemic trend

The second epidemic wave peaked in the United Kingdom during the first two weeks of November (see figure below). A slow decrease in new cases and new hospitalisations was observed up to mid-December. Since then, a sharp increase has been observed, with an acceleration in the daily hospital admission rate during the last week of December. This increase has put pressure on the healthcare system in some parts of the United Kingdom.

**Figure 3. Multiple daily epidemiological indicators of interest in the United Kingdom as of 15 January 2021, and key non-pharmaceutical interventions**

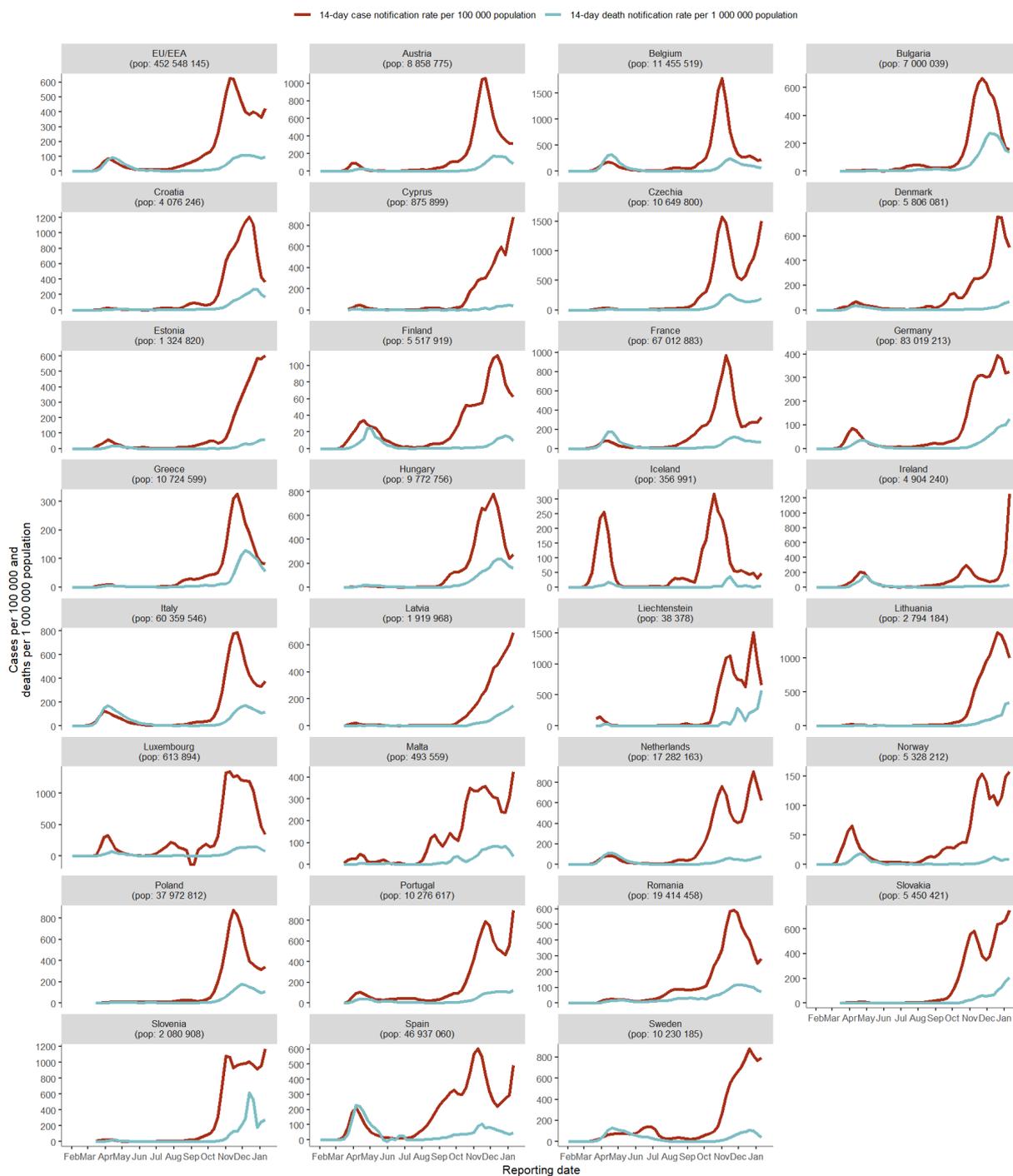


**Sources:** Epidemiological daily indicators retrieved as of 26 December 2020 ('Cases by date reported', 'Deaths within 28 days of positive test by date reported', 'Patients admitted to hospital', 'Patients in hospital' and 'Patients in mechanical ventilation beds') [103]. The source of weekly positive rate time series is ECDC's [Data on testing for COVID-19 by week and country as of week 1 2021](#) [104]. The vertical dotted lines represent the bank holidays (25 December 2020 and 1 January 2021) during the end-of-year festive season.

# Annex 2

**Figure 1. 14-day COVID-19 case and death notification rates in the EU/EEA, as of 11 January 2021**

Regional totals as of 11 Jan 2021: 16 938 330 cases (earliest 2020-W04, latest 2021-W01), 401 535 deaths (2020-W07, 2021-W01)



ECDC. Figure produced 14 January 2021. Source: Epidemic intelligence, national weekly data