



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Update of international public health agency assessments of the evidence in relation to the Omicron (B.1.1.529) variant

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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

Version history

Version number	Date	Details
V1.0	5 January 2022	
V2.0	19 January 2022	Updated review of international public health agency assessments as of 18 January 2022. Removed epidemiological data from this report and added to a separate and new report named "Epidemiological data in relation to the Omicron (B.1.1.529) variant."

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Key points

- HIQA commenced a [rolling summary](#) of the scientific evidence on Omicron on 6 December 2021. The most recent [report](#), based on the included scientific information available as of 4 January 2022, was submitted to NPHET on 5 January 2022. A further update was requested ahead of the NPHET meeting that took place on 20 January 2022, and is presented in this report.
- For the present report, information was collated up to 18 January 2022 from the following agencies and or authorities: European Centre for Disease Prevention and Control (ECDC), Norwegian Institute of Public Health (NIPH), Statens Serum Institut (SSI) (Denmark), South African National Institute for Communicable Diseases (NICD), UK agency websites, including UK Health Security Agency (UKHSA), US Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO).

Transmissibility and Transmission:

- There was strong acknowledgement across agencies and authorities that Omicron is associated with a substantial growth advantage over Delta, as highlighted by the speed at which it became the dominant variant in many countries.
- The WHO, the UKHSA and the NIPH have stated that immune evasion is probably the most important contributor to this growth advantage. However, there was less certainty on whether Omicron is inherently more transmissible than Delta or whether other factors (including a higher proportion of asymptomatic infectious individuals, shorter serial intervals and generation time, and a higher degree of infectivity in the upper respiratory tract) play a contributory role.

Virulence:

- Emerging evidence is available from laboratory, animal and epidemiological studies. While there was a consensus across agencies and authorities that, compared with similar stages of previous waves (including Delta), Omicron is associated with less severe disease, the agencies and authorities had slightly nuanced interpretations of these data:
 - The WHO concluded that data suggest a reduced risk of hospitalisation for Omicron compared with Delta and potentially a reduction in severity

among hospitalised patients. They called for further data to better understand the full clinical picture of Omicron.

- The ECDC concluded that the current limited and preliminary evidence suggests that Omicron has a less severe clinical presentation than that associated with the Delta variant. However, they noted that the applicability of the early evidence is uncertain and that Omicron may not present as a less severe illness in all populations (for example, those without prior immunity).
- The UKHSA concluded with high confidence that in an adult population, the relative risk of hospitalisation is lower with Omicron than with Delta. However, they noted an increased number of hospitalisations among young children has been observed with Omicron, and while early data suggest admitted children are not severely unwell, more data are required.
- The NIPH concluded that Omicron appears to cause less severe disease than Delta in all age groups, including children. The NIPH noted early data suggesting that the already low risk of severe disease associated with COVID-19 in children appears to be further reduced with Omicron.

Immune escape, and vaccine efficacy and effectiveness:

- There was strong consensus across agencies and authorities that Omicron has greater immune evasion than Delta. This may be the most important factor in its growth advantage over Delta.
- Laboratory studies have reported a substantial decline in neutralising titres against Omicron compared with other variants in both vaccinated and convalescent individuals, though the cellular immunity mediated response was found to be largely preserved. Real-world studies have shown that vaccine effectiveness (VE) against symptomatic disease and hospitalisation for fully vaccinated individuals (two doses) is lower for Omicron than Delta. Administration of a booster restores protection to a higher level. However, waning occurs over time and occurs more rapidly with Omicron than Delta.
- A study conducted by the UKHSA found that the highest risk of symptomatic and asymptomatic Omicron infection was in unvaccinated individuals with no prior history of infection. Administration of a booster dose to those vaccinated increased the protective effect, even in those with prior infection.

- Surveillance data from UK, Denmark, Israel and South Africa have reported high levels of reinfection due to Omicron. For example, in England there were 106,297 possible reinfections identified in provisional figures for the week ending 2 January 2022, accounting for 9.5% of all SARS-CoV-2 infections that week.

Treatment efficacy and effectiveness:

- There was no new assessment regarding the potential impact of Omicron on treatment efficacy and effectiveness provided by any of the included agencies and authorities.

Test accuracy:

- The UKHSA provided an update on the utility of S-gene target failure (SGTF) as an early indicator for the prevalence of Omicron. As the prevalence of the Omicron genome lineage BA.2, which is not associated with SGTF, is increasing across the UK, the UKHSA concluded that SGTF is no longer sufficient to assess the overall spread of Omicron.
- The SSI and NIPH concluded that the available evidence suggests that antigen tests would detect Omicron to the same degree as they detect other variants, if the virus is present in large enough quantities at the location of sampling.

Overall assessments of risk and impact:

- There was a consensus across agencies and authorities that the overall level of risk to public health associated with Omicron remains high to very high. While it was noted that countries are at different stages of the Omicron wave, there was an acknowledgement that Omicron was associated with a large surge in infections which would have an impact on the health system and society more broadly, even if the severity is known to be reduced.
- At the SAGE UK meeting held on 7 January 2022, it was stated, with medium confidence, that unlike in previous waves, ICUs are not likely to be the part of the health system under most pressure in the Omicron wave.

Background

HIQA commenced a [rolling summary](#) of scientific evidence in relation to the SARS-CoV-2 'Omicron' variant on 6 December 2021 at the request of the Department of Health. The most recent report, based on information available as of 4 January 2022, was submitted to NPHET on 5 January 2022 (see publication available [here](#)). A further update, was requested ahead of the NPHET meeting that took place on 20 January 2022.

Approach to summarising the evidence

Due to time constraints, the approach taken primarily involved identifying and summarising assessments of the scientific evidence as published by public health agencies and national authorities. The present report collated information from publications published after the 5 January 2022 version of this report was finalised, up to 18 January 2022.

Information was collected from the following agencies and or authorities:

- European Centre for Disease Prevention and Control (ECDC)
- Norwegian Institute of Public Health (NIPH)
- Statens Serum Institut (SSI) (Denmark)
- South African National Institute for Communicable Diseases (NICD)
- UK agency websites, including UK Health Security Agency (UKHSA)
- US Centers for Disease Control and Prevention (CDC)*
- World Health Organization (WHO).

** No new scientific information on Omicron has been provided by the CDC since the previous report submitted on 5 January 2022.*

Information is presented according to the following major headings:

- Transmissibility and transmission
- Virulence
- Immune escape, and vaccine efficacy and effectiveness
- Treatment efficacy and effectiveness

- Test accuracy

- Overall assessments of risk and impact.

Summary of agency assessments

Transmissibility and Transmission

- The **WHO** published its most recent technical brief on Omicron on 7 January 2022.⁽¹⁾ The WHO noted that there was increasing evidence to indicate that immune evasion is contributing to the rapid transmissibility of Omicron, but that more data was needed to identify the association between immune evasion and transmissibility and to investigate the transmission dynamics. On the basis of findings of a vaccine trial study conducted in South Africa,⁽²⁾ it was suggested that the higher proportion of asymptomatic infections observed with Omicron compared with all previous strains of SARS-CoV-2, may be further contributing to transmission of Omicron. Analysis based on preliminary data from the Republic of Korea indicated that the shorter serial intervals (that is, the time between successive cases in a chain of transmission) of Omicron (2.2 days compared with 3.3 days for Delta) may further contribute to the higher transmissibility of Omicron.^(3, 4) The WHO concluded that data from Denmark, South Africa, the UK, Canada and the USA suggest a reduced risk of hospitalisation for Omicron compared with Delta; and in the UK, a reduction in severity among hospitalised patients. However, the WHO noted that more evidence was required to support such findings.
- The most recent **UKHSA** Omicron risk assessment was published on 12 January 2021 (See "Overall assessment of risk and impact" below for more detail).⁽⁵⁾ In this updated risk assessment, the UKHSA maintained its assessment that Omicron displayed a pronounced growth advantage over Delta due to its rapid rise to dominance in the UK and in other countries (red risk status, high confidence). The UKHSA stated with high confidence that immune evasion is a substantial contributor to the growth advantage, but the very high growth rate and laboratory findings raise the possibility that other properties (for example, transmissibility) may also be contributing factors.
 - In relation to transmissibility specifically, the UKHSA maintained their assessment that Omicron is at least as transmissible as Delta (amber risk status, low confidence). It noted laboratory studies demonstrating that it is biologically plausible that Omicron is inherently more transmissible than Delta, particularly with regard to the potential for increased replication in the upper airways. However, it was noted that this assessment is of low confidence, and further studies are needed to understand the relative transmissibility of Omicron compared with Delta.

- The **NIPH** published an updated risk assessment on 12 January 2022.^(6, 7) The NIPH acknowledged that Omicron has greater transmissibility than Delta, potentially two-fold higher. Based on accumulating evidence, the NIPH concluded that this increased transmissibility may be due to several contributory factors:
 - greater immune evasion by Omicron, which was deemed to be probably the most important factor
 - higher infectivity of Omicron in the upper respiratory tract, enabling easier infection
 - shorter generation time (due to shorter latency time) of Omicron, enabling faster spread of the epidemic. While uncertainty was noted in relation to this factor, it was considered a potential contributor.

Virulence

- In an updated technical brief published on 7 January 2022,⁽¹⁾ the **WHO** referred to a UK preprint study published on 3 January 2022 that reported that Omicron showed a reduction in replication compared with Delta and the ancestral SARS-CoV-2 strain.⁽⁸⁾ It also noted a preprint study by Chan et al.⁽⁹⁾ that observed that Omicron replicated ten times less efficiently compared with Delta in human lung tissue. The WHO stated that the most up to date animal studies yielded similar findings showing that Omicron-infected animals had less lung pathology and milder disease compared with Delta-infected animals.⁽¹⁰⁻¹²⁾
- The **ECDC** published their most recent 'weekly epidemiological update' in relation to Omicron on 14 January 2022, which included data as of 13 January 2022.⁽¹³⁾
 - At the time of reporting, the ECDC concluded that the current limited and preliminary evidence suggests that Omicron has a less severe clinical presentation than that associated with the Delta variant, but that it was premature to make a complete assessment of Omicron's severity. However, they noted that given the exponential growth advantage of Omicron and the high numbers of cases, any potential benefits from a lower observed severity would be short-lived and outpaced by the sheer number of severe outcomes over time. The combination of higher growth rate and immune evasion indicated that any potential advantage Omicron may have in terms of decreased severity, could be countered by increased community infection rates that would lead to a substantial additional burden for hospital and primary care than during previous waves.
 - The ECDC highlighted important key considerations when interpreting the evidence to date. They stated that the true risk of severe infection

associated with Omicron may be underestimated by the large numbers of vaccinated or previously infected people, which was not the case in the beginning of preceding waves. They also noted that the studies considered did not account for waning immunity or the likely large amount of under-ascertained reinfections, which could lead to an overestimation of the decrease in severity. In addition, accounting for the relatively young age of those infected to date, the ECDC noted that there were limited data on severity among older age groups and people with underlying risk factors. Therefore, it was stated that early results may not represent the entire Omicron wave and the clinical profile of Omicron may change with additional evidence.

- The ECDC report considered evidence from a number of sources including the UKHSA Technical Briefing 33 as well as data from Scotland, South Africa and the US. These were discussed as follows:
 - A Scottish study identified a reduced hospitalisation risk associated with Omicron compared with Delta, while the rate of possible reinfection for Omicron was ten times that of Delta.⁽¹⁴⁾ Vaccinated individuals with a third or booster dose were found to have a 57% (95% CI 55-60) lower risk of experiencing symptoms following Omicron infection compared with Delta.
 - A preprint study from South Africa,⁽¹⁵⁾ found that despite recording a higher number of cases during the Omicron wave, hospital admission rates were lower (4.9%) than in the previous waves (Beta: 18.9%, Delta: 13.7%) and fewer patients had severe disease (Omicron: 28.8% vs Beta: 60.1% and Delta: 66.8%). Omicron hospitalised patients were found to be 73% less likely to be severely ill than patients admitted during the preceding waves (aOR 0.27, 95% CI 0.25 to 0.31). Severe disease was defined in this study as one or more of the following: development of acute respiratory distress syndrome, receipt of oxygen or invasive mechanical ventilation, treatment in high care or ICUs or death. The median length of hospital stay of four days (IQR 2-6) was also shorter in the most recent wave than in the Beta and Delta waves (7 days (IQR 4-11) and 8 days (IQR 4-14), respectively).
 - A shorter median length of hospital stay and a reduced need for respiratory support than that observed for the previous variants were also reported in a preprint publication from Texas.⁽¹⁶⁾

- A preprint study from Southern California was also referenced, which reported a reduced risk of hospitalisation, ICU admission and mortality for Omicron cases compared with Delta.⁽¹⁷⁾ The median duration of hospital stay for symptomatic patients was approximately 70% (~3.4 days) shorter for Omicron cases.
- With regards to the effect of severity on population burden of disease, the ECDC noted that the intrinsic severity of Omicron may be different between countries with differing levels of vaccine-derived and natural immunity. Thus it is becoming increasingly difficult to generalise disease severity across countries. However, given the conclusive evidence on the exponential growth advantage of Omicron over Delta, the ECDC stated that even a large reduction in severity would ease the pressures felt from increased hospital admissions for only a very short time.
- The most recent **UKHSA** Omicron risk assessment was published on 12 January 2021 (See "Overall assessment of risk and impact" below for more detail).⁽⁵⁾ In the latest risk assessment, the infection severity domain has been sub-divided into severity in *adults* and severity in *children*. For adults, the most recent risk assessment is unchanged in that the UKHSA has classified the risk associated with infection severity in adults as 'green'. That is, there is evidence of a less severe clinical picture or lower infection fatality than from Delta infections. The UKHSA stated that there is a reduction in the relative risk of hospitalisation associated with Omicron compared with the Delta variant. This assessment has been upgraded from low to high confidence since the previous assessment, given the increasing evidence to support this conclusion. The UKHSA provided the following rationale for their assessment:
 - Multiple laboratory studies have indicated considerable change in phenotype, including changes in cell entry and fusogenesis, although these cannot be directly correlated to virulence.
 - Preliminary animal studies were found to be consistent with reduced virulence.
 - Several UK analyses found a reduction in the relative risk of hospitalisation for adult Omicron cases compared to Delta, consistent with data from South Africa.
 - Available data suggests that the observed reduction in risk of hospitalisation in adults is likely to be partly due to a reduction in

intrinsic severity of the virus and partly due to protection provided by prior infection or vaccination.

- The **UKHSA** risk assessment has classified the risk associated with infection severity in children as 'amber'; that is, there may be more severe clinical picture or higher infection fatality than from Delta infections in this population.⁽¹⁸⁾ However, this assessment was associated with low confidence due to insufficient data. The UKHSA noted that increased numbers of hospital admissions in young children were reported in the UK and some other countries. In the UK, the number of paediatric admissions with COVID-19 infection began to rise from 26 December 2021, from an average of 40 admissions per day to 120 per day, a three-fold rise in two weeks.
 - Further analysis by age group found that the rise was most rapid among children under five years and highest in infants aged under one year. However, early data suggests that admitted children are not severely unwell with Omicron infection. It was stated that further analyses are required to compare the risk of hospitalisation between Omicron and Delta and to assess the clinical nature of the illness in children.
- Separately, the **UKHSA** conducted a study comparing symptoms between Omicron and Delta cases.⁽¹⁸⁾ Analysis of test and trace data from 1 December 2021 to 28 December 2021 showed that sore throat appeared to be more frequent in Omicron cases compared with Delta cases (53% vs 34%, odds ratio (OR) 1.93, 95% CI: 1.88 to 1.98), whereas loss of smell was reported less often by Omicron cases compared with Delta cases (13% vs 34%, OR 0.22, 95% CI: 0.21 to 0.23). However, it should be noted that another recent study conducted in the UK found an increase in sore throat symptoms among PCR-negative cases, indicating that sore throat may not be a specific predictor for infection with Omicron.
- The **NIPH** published an updated risk assessment on 12 January 2022.^(6, 7) The NIPH concluded that Omicron appears to cause less severe disease than Delta in all age groups. It was stated that the hospitalisation risk associated with the Omicron variant may only be one-third that of Delta, with the risk of ICU admission reduced further and the length of hospital stay shortened. In its latest modelling, the NIPH considered a reduction in the risk of hospitalisation of 50% or 70% in Omicron-infected patients compared with those infected with Delta.

- Using Norwegian surveillance data, the NIPH noted a 69% reduction in the risk of COVID-10-related hospitalisation with Omicron compared with Delta.⁽¹⁹⁾ The NIPH noted that there were several potential factors contributing to its lower observed severity to date:
 - Lower inherent severity (virulence) as indicated by laboratory studies demonstrating a lower capacity to infect lung cells. If the Omicron variant has lower inherent virulence, then the disease would become milder in all populations.
 - The immune evasion properties of Omicron, may permit the variant to infect a wider range of individuals. This may include infection of individuals with a history of vaccine-induced or natural immunity who are at lower risk of progressing to severe disease. It was noted that should this be an important contributor to the lower observed severity, then the clinical severity may vary between countries according to their population-level immunity.
 - The age distribution of those infected. Given that the spread of Omicron was greatest among younger populations initially, who normally do not experience severe COVID-19, worse outcomes may be observed when Omicron spreads to a greater extent among older adults. It was noted that early analysis indicates that the low risk of severe disease associated with COVID-19 in children appears to be further reduced by Omicron.

Immune escape, and vaccine efficacy and effectiveness

- In the updated technical brief on the Omicron variant published by the **WHO** on 7 January 2022,⁽¹⁾ it was stated that immune evasion after past infection or vaccination plays a significant role in the rapid growth in Omicron cases. It was noted that the emerging evidence suggests a substantial decline in neutralising titres against Omicron compared with other variants in both vaccinated and convalescent individuals. However, given the risk of observational biases with early data, the WHO highlighted the need for caution in its use.
 - A meta-analysis by Netzl et al. aggregated data from studies reporting on Omicron antibody neutralisation titres until 22 December 2021.⁽²⁰⁾ This study found that with convalescent sera, the fold drop in neutralisation associated with Omicron, compared with wild type SARS-CoV-2, was substantial (20x). This finding was complicated by the fact that the majority of titres associated with Omicron were below their individual assays' limit of detection. When limited to individuals who had received three doses of vaccine or who had prior infection followed by two doses

of vaccine, a seven-fold reduction in neutralisation was observed. Importantly, almost all samples from third dose vaccines were obtained within one month of the last dose administration. It was concluded that a reduction in antibody titres to Omicron may contribute towards the increased risk for reinfection.

- Multiple datasets on cellular immunity have concluded that, in those that had been previously infected and or vaccinated, 70-80% of CD4+ and CD8+ responses are maintained for Omicron infection.⁽²¹⁻²⁵⁾ Reports have also noted that well-preserved cellular immunity to Omicron may assist in protecting against severe disease and death, and likely underlies the observed reduced risk of hospitalisation for those with reinfection due to the Omicron variant.⁽²⁶⁾
- Surveillance data from the UK,⁽²⁶⁾ Denmark⁽²⁷⁾, Israel⁽²⁸⁾ and South Africa⁽²⁹⁾ have reported high levels of reinfection due to Omicron. For example, the risk of reinfection in England with the Omicron variant was estimated to be 5.4 (95% CI: 4.87 to 6.00) fold higher compared with the Delta variant. The relative risks were 6.36 (95% CI: 5.23 to 7.74) and 5.02 (95% CI: 4.47 to 5.67) for unvaccinated and vaccinated cases, respectively. It was estimated that the protection against reinfection by Omicron after a past infection may be as low as 19%.⁽³⁰⁾
- Analysis of preliminary experimental data based on 16 Pfizer vaccinated samples indicated that there might be a more preserved cellular immunity-mediated protection against severe disease based on the prediction that 70% of Omicron epitopes may not be affected by T-cell recognition.⁽³¹⁾ Two preprint studies evaluating T-cell responses in vaccinated persons found that neutralisation responses were significantly reduced against Omicron, but that little effect on cellular immunity against both the Delta and Omicron variants was observed.^(32, 33)
- One preprint study reported a reduction in binding antibody levels against Omicron, but the binding reduction was mostly retained in vaccinated individuals.⁽²⁰⁾
- The WHO reported identified nine studies that have evaluated the effectiveness of four vaccines (BNT162b2, mRNA-1273, Ad26.COV2.S, and AstraZeneca-Vaxzevria) using early data from the UK, Denmark, Canada, and South Africa. Compared with Delta, the studied vaccines were found to be less effective against infection, disease and hospitalisation due to Omicron. Evidence showed that booster doses increased vaccine

effectiveness, but that effectiveness reduced over time. It was noted that evidence from two studies concluded that although the vaccine effectiveness against hospitalisation remained high, it was lower than against Delta. The WHO noted that further evidence was required in this regard.

- Analysis by researchers at Imperial College London estimated the vaccine effectiveness against symptomatic infection from Omicron was 0% to 19% with two doses, and 54% to 77% after a booster dose.⁽³⁴⁾ They also found that the hazard ratios for hospitalisation were generally lower for Omicron than for Delta for those who received AstraZeneca-Vaxzevria as primary vaccination, while Omicron hazard ratios were similar to Delta among those who received Pfizer BioNTech-Comirnaty and Moderna's mRNA-1273 as primary vaccination.
- The recently established **WHO** Technical Advisory group on COVID-19 Vaccine Composition provided an interim Statement on COVID-19 vaccines in the context of the circulation of Omicron on 11 January 2022.⁽³⁵⁾ The key points from this statement were as follows:
 - It was considered that the composition of current COVID-19 vaccines may need to be updated. This should be done to ensure that COVID-19 vaccines continue to provide an adequate level of protection against infection and disease by variants of concern, including Omicron and future variants.
 - The requirement for vaccines to elicit immune responses that are broad, strong, and long-lasting in order to reduce the need for successive booster doses.
 - Suggested strategies included: monovalent vaccines against the predominant circulating variant, multivalent vaccines containing antigens from different variants of concern, and a variant-proof vaccine or pan coronavirus vaccine.
- The most recent 'weekly epidemiological update' in relation to Omicron by the **ECDC** was published on 14 January 2022.⁽¹³⁾ The report noted that early studies suggested that current vaccines may be less effective against Omicron infection, although they still provide protection against hospitalisation and severe disease. Commentary on the available data to date included a reference to a UKHSA analysis, as discussed below, in addition to the following:
 - A preprint of a Canadian study, which assessed the vaccine effectiveness of mRNA vaccines, found that two doses of an mRNA vaccine were not

protective against Omicron infection (Vaccine Effectiveness (VE) 6%, 95% CI: -25 to 30%).⁽³⁶⁾ A third dose provided some protection against Omicron infection (VE 37% (95% CI: 19 to 50%)) in the immediate term, but that this was substantially less than against Delta (VE 93% (95% CI: 92-94%)), seven or more days after the third dose. The study highlighted that results may be confounded by behaviours that were unable to be accounted for and that duration of the protection and effectiveness against severe disease are uncertain.

- Another preprint study from the US, sponsored by the vaccine manufacturer Moderna, reported a VE of 30.4% (95% CI: 5.0 to 49.0%) against Omicron infection 19 to 90 days after two doses of the Spikevax (Moderna) vaccine.⁽³⁷⁾ This declined to 15.2% (95% CI: 0.0% to 30.7%) after 91 to 180 days. A third (booster) dose increased the effectiveness to 62.5% (95% CI: 56.2 to 67.9%). The study also reported a considerably lower VE against Omicron infection among immunocompromised individuals: 11.5% (95% CI: 0.0% to 66.5%) when compared with the general population 63.6% (95% CI: 57.4% to 68.9%).
- Earlier studies, from the UK⁽³⁸⁾ and Denmark,⁽³⁹⁾ have shown a significantly reduced and declining vaccine effectiveness against symptomatic disease with Omicron compared to Delta. These studies also reported that a booster dose increased the vaccine effectiveness, although not as efficiently as against infection with Delta. The additional protection from booster doses against infection with Omicron was also confirmed in a recent study from Scotland (as discussed above).⁽¹⁴⁾
- Regarding hospitalisations, estimates of vaccine effectiveness from the UKHSA⁽⁴⁰⁾ and South Africa⁽⁴¹⁾ have indicated that the protection against severe disease from Omicron infection is higher (around 70% after primary vaccination) than the protection against mild infections, and that protection increases after a third dose of vaccine.
- On 7 January 2022, the **UKHSA** provided an updated analysis⁽⁴²⁾ on the effectiveness of three doses of COVID-19 vaccines against symptomatic COVID-19 and hospitalisation in those aged 65 and older.
 - The analysis found that in all periods, VE against symptomatic disease with Omicron was significantly lower than with Delta and wanes rapidly and that protection against hospitalisation was much greater than that against symptomatic disease. Vaccine effectiveness against symptomatic disease from Omicron for the various vaccines may be summarised as follows:

- ChAdOx1-S (AstraZeneca) and a booster dose of an mRNA vaccine: VE ranged from 62% to 65% at two to four weeks post-third dose, dropping to 48% and 56% at 5-9 weeks for the BNT162b2 (Pfizer/BioNTech) and mRNA-1273 (Moderna) booster, respectively. For the BNT162b2 (Pfizer/BioNTech) booster, VE dropped further to 32% beyond 10 weeks.
- Two doses of BNT162b2 (Pfizer/BioNTech) followed by a BNT162b2 (Pfizer/BioNTech) booster: VE was 65% at two to four weeks post the booster, dropping to 49% at five to nine weeks and 31% beyond 10 weeks.
- Two doses of BNT162b2 (Pfizer/BioNTech) followed by an mRNA-1273 (Moderna) booster: VE was 70% at two to four weeks post the booster, dropping to 57% at five to nine weeks.
- For all vaccines combined, receiving three doses of a vaccine was associated with a VE of 94% (95% CI: 89 to 97) against hospitalisation with the Omicron variant, two to nine weeks post the booster dose. The VE against the combined outcome of hospitalisation or symptomatic disease was 89% (95% CI 80 to 95) at 10+ weeks post booster.
- The UKHSA noted that results should be interpreted with caution due to low numbers and the possible biases related to differences in the population groups.
- On 14 January 2021, the **UKHSA** published a technical briefing with an update on vaccine effectiveness associated with Omicron with a data cut off of 6 January 2022 used in the analysis.⁽¹⁸⁾
 - A test-negative case-control design was used to estimate vaccine effectiveness by primary vaccine series, variant and time after dose 2 and dose 3 for the outcomes symptomatic disease and hospitalisation. Cases in adults aged 18 years and older were included. Estimates were adjusted for age, gender, the previous positive test, region, ethnicity, travel history and clinically extremely vulnerable status.
 - Cases were defined as the Omicron or Delta variant based on whole-genome sequencing, genotyping or S-gene target status on PCR testing (236,023 Delta cases and 760,647 Omicron cases).
 - In all periods, vaccine effectiveness was lower for Omicron compared to Delta. BNT162b2 (Pfizer/BioNTech) estimates against Omicron are presented in Figure 1 below.

- In those who had only completed a two-dose schedule, vaccine effectiveness against symptomatic disease with Omicron was 10% or less by 20 weeks after dose two. After a booster dose, vaccine effectiveness for symptomatic disease initially increased but later fell over time. Vaccine effectiveness by primary vaccine series ranged from around 65 to 75% at 2 to 4 weeks after a booster dose, dropping to 55 to 65% at 5 to 9 weeks and 45 to 50% from 10+ weeks after the booster.
- Hospitalisation was defined as admissions via emergency care 0 to 14 days after a positive test (excluding admissions due to injuries).⁽⁴³⁾ They estimated that vaccine effectiveness against Omicron hospitalisation increased after a booster dose. At 25+ weeks after dose two, vaccine effectiveness was estimated as 44% (95% CI: 30 to 54%), but increased to 92% (95% CI: 89 to 94%) two to four weeks after a booster dose. Vaccine effectiveness was 83% (95% CI :78 to 87%) 10+ weeks after dose 3. Combining the dose 3 periods, overall vaccine effectiveness 2+ weeks after the booster was 89% (95% CI: 86-91%). The UKHSA suggested that further data are needed to estimate the duration of protection against hospitalisation.

Figure 1. Vaccine effectiveness against symptomatic disease by period after dose 1 and dose 2 for Delta (black squares) and Omicron (grey circles) for recipients of 2 doses of Pfizer vaccine as the primary course and Pfizer or Moderna as a booster (Taken from UKHSA Technical briefing 34)⁽¹⁸⁾

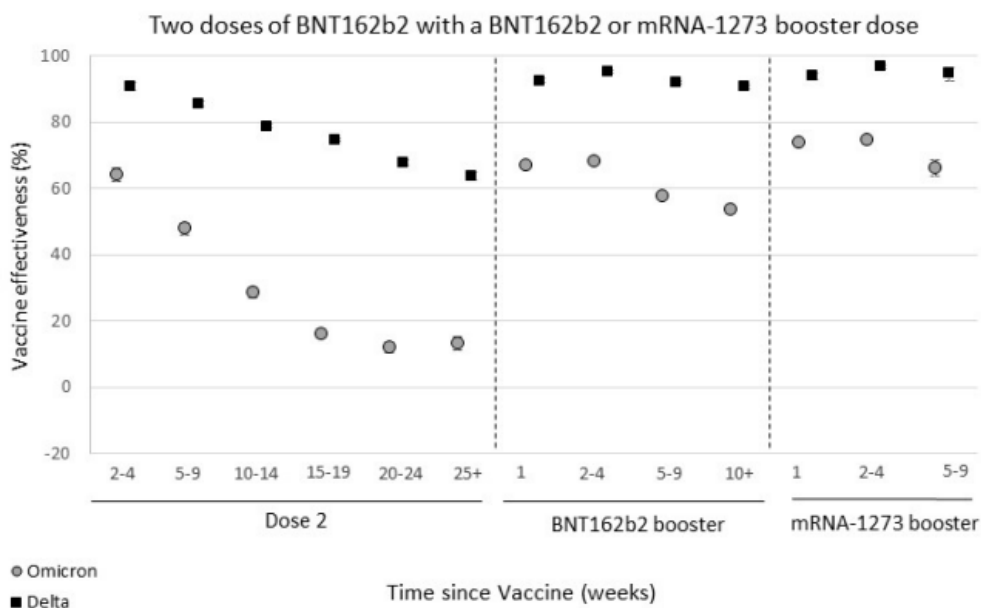


Table 1. Vaccine effectiveness against hospitalisation with Omicron (Adapted from UKHSA Technical briefing 34)⁽¹⁸⁾

Dose	Interval after dose (weeks)	OR v symptomatic disease (95% CI)	HR vs hospitalisation (95% CI)	VE vs hospitalisation (95% CI)
1	4+	0.74 (0.72-0.76)	0.57 (0.38-0.85)	58% (37-72)
2	2 to 24	0.81 (0.8-0.82)	0.45 (0.36-0.56)	64% (54-71)
2	25+	0.94 (0.92-0.95)	0.60 (0.49-0.74)	44% (30-54)
3	2 to 4	0.32 (0.31-0.33)	0.26 (0.19-0.35)	92% (89-94)
3	5 to 9	0.42 (0.41-0.43)	0.29 (0.23-0.37)	88% (84-91)
3	10+	0.50 (0.49-0.51)	0.34 (0.26-0.44)	83% (78-87)

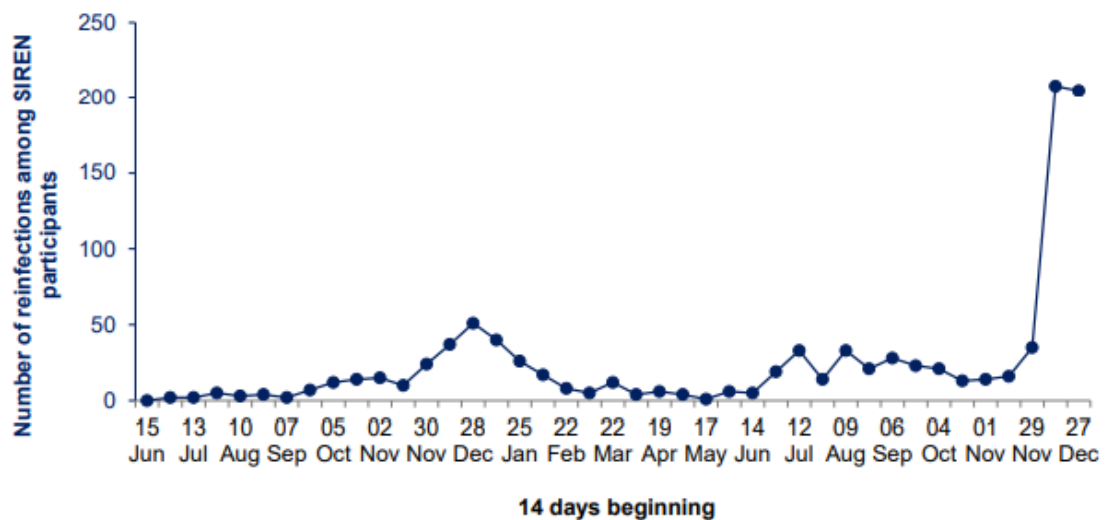
Key: CI- confidence interval, HR- hazard ratio, OR- odds ratio, VE- vaccine effectiveness

- In the 14 January 2022 technical briefing by the **UKHSA**, an update on the SARS-CoV-2 Immunity and Reinfection Evaluation in healthcare workers (SIREN) study was provided.⁽¹⁸⁾ The SIREN study is an ongoing cohort study of over 44,000 National Health Service healthcare workers, recruited from 135 hospital sites across the UK. In this study, participants undergo asymptomatic SARS-CoV-2 PCR testing every two weeks. This cohort had high seropositivity on recruitment (30% before the second wave) and is now highly vaccinated (>95%). The incidence of new infections and potential reinfections in SIREN is monitored on an ongoing basis (Figure 2).

 - Both the number of reinfections and the number of primary infections have rapidly increased since mid-December 2021 through to the latest date of follow-up (9 January 2022).
 - During the fortnight commencing 27 December 2021, approximately 80 of every 1,000 healthcare workers who underwent PCR testing in this study, tested positive for SARS-CoV-2. In total, over 10,000 healthcare workers (approx. 23% of the cohort) were tested during this two-week period.
 - During this same two-week period, over 200 reinfections among study participants were observed (Figure 2). It was noted that data at the latest time point may be affected by delayed reporting and hence this estimate may increase. Of note, prior to December 2021, the absolute number of

reinfections detected every fortnight among this cohort was consistently lower than 50. Data were first reported on 15 June 2020.

Figure 2 Number of reinfections among SIREN participants in the UK from 15 June 2020 to 9 January 2022 (Taken from UKHSA Technical briefing 34)⁽¹⁸⁾



Notes: Data are preliminary, and includes all possible reinfections flagged, but some may subsequently be excluded following clinical review. Data at the latest timepoint may be affected by delayed reporting.

- A subgroup analysis of the SIREN study assessed the protection against Omicron infections (PCR positive infection) provided by COVID-19 vaccination and or prior SARS-CoV-2 infection between 1 December 2020 and 4 January 2022 (n=18,464 participants).
- Participants were categorised by vaccination and prior infection status on 30 November 2021. By this cut-off date, 60% (n=11,084) had no prior infection, 40% (n=6,974) had prior infection, and the majority (not quantified) had received three doses of COVID-19 vaccine, primarily (not quantified) the BNT162b2 (Pfizer BioNTech) mRNA vaccine.
- The results highlighted the increased protective effect of a booster dose of the COVID-19 vaccine, even in those with prior infection, against symptomatic and asymptomatic Omicron infections compared with uninfected unvaccinated participants (108.5 infections per 10,000 person days), who experienced the highest infection risk (Table 2). The lowest observed incidence was among those with prior infection who had received three doses (31 infections per 10,000 person days).

- An incremental benefit from each vaccine exposure was observed, even in those who had a prior infection (confirmed through antibody or detection through asymptomatic and symptomatic testing).
- It was noted that this was an early unadjusted output with uncertainty in the estimates.

Table 2. Incidence of Omicron infections in the SIREN cohort between 1 December 2021 and 4 January 2022 by vaccination and prior infection status on 30 November 2021 (n=18,464) (Adapted from UKHSA Technical briefing 34)⁽¹⁸⁾

Status	Number of participants	Number of days of follow up	Number of infections	Crude incidence rate (per 10,000 person days)	Vaccine effectiveness (%) (100 x 1-IRR)	95% CI
No previous infection; vaccine status on 30 November 2021						
Unvaccinated	87	1,935	21	108.5	Ref	Ref
Vaccinated 2 dose	1,156	24,801	182	73.4	32%	-6% to 57%
Vaccinated 3 dose	9,841	225,126	937	41.6	62%	41% to 75%
Prior infection; vaccine status on 30 November 2021						
Unvaccinated	255	5,750	35	60.9	44%	4% to 67%
Vaccinated 2 dose	1,333	28,255	123	43.5	60%	36% to 75%
Vaccinated 3 dose	5,386	121,762	377	31.0	71%	56% to 82%

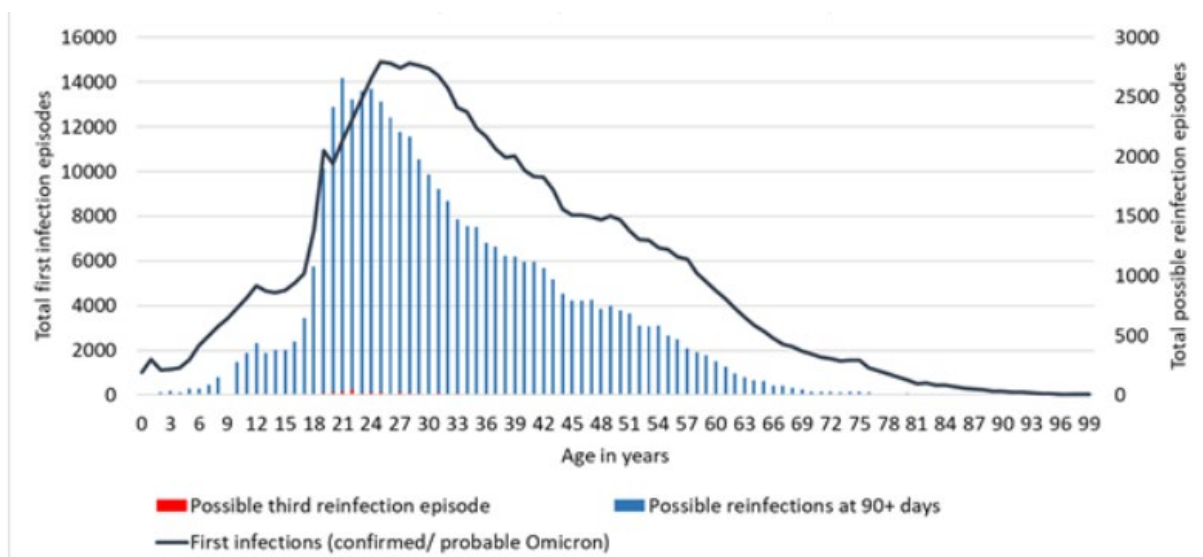
Notes: IRR Incidence Rate Ratios. IRR are not adjusted.

- In the **UKHSA** Technical briefing published on 14 January 2022,⁽¹⁸⁾ data on possible reinfections (an interval between two sequential positive SARS-CoV-2 test results (PCR or lateral flow test) of ≥ 90 days) in England were provided. It was noted that there had been a sharp rise in the overall reinfection rate since mid-December 2021, which was disproportionate to the increase in first infections. There were 106,297

possible reinfections identified in provisional figures for week 52 (ending 2 January 2022), accounting for 9.5% of all SARS-CoV-2 infections that week.

- The overall age distribution of possible Omicron reinfections (positive tests ≥ 90 days apart) closely followed the overall distribution of first infections by Omicron in England (between 1 November and 30 December 2021), with the highest numbers seen in those aged 20-30 (Figure 3). It was noted that episodes of possible third infections (that is individuals reinfected twice) had been observed in young people aged between 18 and 33, though these were reported to be rare events.

Figure 3. Age profile of first episodes of infection and possible reinfection (90+ day interval between sequential positive test results) with Omicron (1 November to 30 December 2021) (Taken from UKHSA Technical briefing 34)⁽¹⁸⁾



- The **NIPH** published an updated risk assessment on 12 January 2022.^(6, 7) In their assessment, the NIPH concluded that, based on accumulating evidence, Omicron has greater immune evasion than Delta, and that this factor may be the most important reason for its growth advantage over Delta.

Treatment efficacy and effectiveness

- The **WHO** updated its technical brief on the Omicron variant on 7 January 2022.⁽¹⁾ A similar statement was made to that in the previous version with respect to concerns regarding the efficacy of some neutralising monoclonal antibodies against Omicron.

Test accuracy

- In the updated technical brief published by the **WHO** on 7 January 2022,⁽¹⁾ similar statements were made to that in the previous version of the technical brief regarding test accuracy.
- The **UKHSA** provided an update on the utility of S-gene target failure (SGTF) as an early indicator for the prevalence of Omicron in their most recent technical briefing, published on 14 January 2022.⁽¹⁸⁾ Certain PCR tests (such as the TaqPath assay) can be used to screen for SGTF, which has been assumed to be a proxy for the Omicron variant. These assays test for the presence of three different SARS-CoV-2 genes (Spike, N and ORF1ab); SGTF occurs when N and ORF1ab are detected, but S is not. It was noted that the Omicron genome lineage BA.1 is associated with SGTF, however, the Omicron lineage BA.2 is S-gene target positive (SGTP). As of 1 January 2022, BA.2 accounted for 5% of SGTP and this proportion was noted to be increasing. Thus, the UKHSA concluded that SGTF is no longer sufficient to assess the overall spread of Omicron.
- On 6 January 2022, the **SSI** of Denmark published the findings of its qualitative assessment of the ability of ten antigen detection tests used in Denmark to detect Omicron, Delta and wild-type SARS-CoV-2.⁽⁴⁴⁾ The tests examined were:
 - Panbio - COVID-19 Ag RAPID TEST (Abbott)
 - SARS-COV-2 Rapid Antigen test (Roche)
 - Flowflex SARS-CoV-2 Antigen Rapid Test (Acon Biotech)
 - Onsite Covid-19 Ag Rapid Test (CTK Biotech)
 - SARS-COV-2 Rapid Antigen test Nasal (Roche)
 - Standard Q, Covid-19 Ag Nasal (SD Biosensor)
 - BIOSYNEX COVID-19 Ag BSS (BIOSYNTEX)
 - SARS-COV-2 Antigen Self-test Nasal (Roche)
 - Rapid SARS-COV-2 Antigen Test Card (Boson Biotech)
 - Covid-Rapid, SARS-COV-2 Antigen (api Pharma).

- The study found that all examined antigen detection tests were able to detect both Delta and Omicron at levels comparable to the detection of wild-type SARS-CoV-2. Of note, a quantitative assessment of analytical sensitivity was not undertaken and so comparison of performance between tests was not possible.
- On 12 January, the **NIPH** published an updated risk assessment on the impact of the Omicron variant in Norway.^(6, 7) In the report, NIPH commented on the potential impact of the Omicron variant on the performance of antigen tests. The NIPH concluded that overall, current knowledge suggested that antigen tests would detect Omicron to the same degree as it detects other variants, if the virus is present in large enough quantities at the location of sampling. It was noted that some studies indicated that early in the course of an infection, the viral load of Omicron may be higher in the saliva than the nose; however, it was noted that this was still uncertain.

Overall assessments of risk and impact

- On 7 January 2022, the **WHO** updated their technical brief on the Omicron variant.⁽¹⁾ The WHO stated that the overall risk related to Omicron remained very high.
- In the 14 January 2022 weekly epidemiological update, the **ECDC** stated that their Rapid Risk Assessment 18th Update (published 15 December 2021)⁽⁴⁵⁾ on the impact of Omicron remained valid, that is, that the overall level of risk to public health in the EU/EEA associated with Omicron remained **very high**.⁽¹³⁾ The update noted that the very high growth advantage of Omicron is expected to result in even higher overall case notification rates over the coming weeks.
 - Individual member state assessments are also conducted on a weekly basis by the ECDC.⁽⁴⁶⁾ The latest assessments were published on 13 January 2022. The assessment of each country's epidemiological situation is based on a composite score and considers the absolute value and trend of five weekly COVID-19 epidemiological indicators. For week 1 of 2022, all but two EU/EEA Member States (Slovakia and Romania) were categorised as being of high or very high concern. Ireland was deemed to be of very high concern, scoring 8.7 out of 10 (increased from 8.0 the previous week), slightly below the EU/EEA average of 9.3 (increased from 9.0 the previous week).
- The most recent **UKHSA** Omicron risk assessment was published on 12 January 2021,⁽⁵⁾ and is summarised in tabular form below (Table 3). The assessments across all domains remained the same as those published on 22

December 2021,⁽⁴⁷⁾ with the exception of the indicator 'infection severity', which has now been sub-divided into severity in adults and severity in children. For adults, the most recent risk assessment is unchanged, the UKHSA has classified the risk associated with infection severity in adults as 'green', that is, there is evidence of a less severe clinical picture or lower infection fatality than from Delta infections. Given the increasing evidence to support this conclusion, this assessment has been upgraded from low (22 December 2021) to high confidence. The risk assessment has classified the risk associated with infection severity in children as 'amber', that is, there may be more severe clinical picture or higher infection fatality than from Delta infections in this population. However, this assessment is associated with low confidence due to insufficient data.

Table 3. UKHSA Risk Assessment for Omicron (12 January 2022)⁽⁵⁾

<i>Indicator</i>	<i>Red, amber or green status (red = highest risk)</i>	<i>Confidence level</i>	<i>Assessment</i>
<i>Growth advantage</i>	<i>Red</i>	<i>High</i>	<i>Omicron is the dominant circulating variant.</i>
<i>Transmissibility</i>	<i>Amber</i>	<i>Low</i>	<i>Omicron is at least as transmissible as Delta.</i>
<i>Immune evasion (from natural and vaccine-derived immunity)</i>	<i>Red</i>	<i>High</i>	<i>Omicron displays substantial immune evasion properties in the current population context.</i>
<i>Infection severity (adults)</i>	<i>Green</i>	<i>High</i>	<i>Reduction in the relative risk of hospitalisation.</i>
<i>Infection severity (children)</i>	<i>Amber</i>	<i>Low</i>	<i>Insufficient data.</i>

- The UK Scientific Advisory Group for Emergencies (**SAGE**) met on 7 January 2022 with minutes published on 14 January 2022.⁽⁴⁸⁾
 - Several documents were made available for the meeting, including:
 - **SPI-M-O: Consensus statement on COVID-19, 6 January 2022**
 - **SPI-M-O: Medium-term projections, 6 January 2022**

- **Imperial College London: Omicron severity and vaccine effectiveness, 5 January 2022**
 - **UKHSA: Omicron and Delta serial interval distributions from UK contact tracing data, 31 December 2021**
 - **UKHSA: The spread of Omicron and replacement of Delta in the UK, 5 January 2022**
 - **University of Warwick: Omicron modelling, 6 January 2022**
 - **Dynamic CO-CIN report to SAGE and NERVTAG recent cases, 7 January 2022**
 - **CO-CIN: Child admissions and severity by epoch CO-CIN update January 2022, 6 January 2022**
 - **CMMID: Social contacts in the UK from the CoMix social contact survey**
- In light of these documents presented at the SAGE meeting, the following points were noted in the SAGE situation update:
- It was noted that the number of infections is continuing to increase nationally, including in older age groups. The main exception has been a levelling of case numbers in London, due to a decreased incidence in younger age groups, albeit, with a continued increase in older age groups. Furthermore, test positivity rates have continued to increase in most groups.
 - The epidemic in the UK was viewed to have the potential to continue to grow. It was noted that the peak will not be known until after it occurs and will likely occur at different times in different areas among different age groups. It was noted that the spread of infections in older age groups, which is lagging behind younger cohorts, would be an important determinant for the number of hospital admissions.
 - Modelling suggested that non-pharmaceutical interventions implemented in the near future would have little effect on the peak of hospital admission, but could affect overall hospitalisation levels by bringing the epidemic down more quickly (and thereby reducing the number of severe cases). The largest effects of such measures

would be in those parts of the country where Omicron has become dominant more recently. Changes in behaviour, for example if there were a reversal of current interventions (e.g. 'Plan B' in England) before the peak has passed, could increase the overall impact of this wave on hospitalisations.

- There is some evidence (low confidence) that the *median* generation time (the time between someone becoming infected, and that person infecting others) is slightly shorter for Omicron than for Delta, though the *mean* generation time appears similar (low confidence). It was noted that a modest reduction in the generation time could significantly reduce the modelled peak in infections and hospital admissions (high confidence).
- An analysis from Imperial College London suggested a reduction in the risk of hospitalisation of 35-65% for Omicron when compared with Delta in the current wave, depending on the endpoint used. The increasing evidence of lower severity, accumulating evidence on vaccines' effectiveness against hospitalisation, and the likelihood of Omicron's generation time being shorter than Delta's, suggest that of the various scenarios previously considered, the most pessimistic scenarios were no longer viewed to be likely (high confidence). However, it was noted that hospital admissions in England would remain high for some time due to the very high levels of infection and the continued risk of hospitalisation for older and unvaccinated adults.
- Early data from COVID-19 Clinical Information Network (CO-CIN) indicated that the severity of disease being observed in hospital over the last three weeks was lower than that observed in early phases of previous waves, with less need for oxygen, fewer admissions to intensive care, better outcomes, and shorter stays. It was noted that unlike in previous waves, ICUs are not likely to be the part of the health system under most pressure in this wave (medium confidence).
- In addition to the lower intrinsic severity of Omicron as indicated by laboratory studies, it was noted that the observed severity was lower due to the benefit of higher levels of immunity than in past waves. Vaccine effectiveness data show that boosters are highly effective, although waning against symptomatic disease after 10 weeks was observed. It was noted that protection against severe disease was

likely to be better maintained. While there may be a biological mechanism for the observed reduction in severity with Omicron, it was noted that future variants may not necessarily retain these properties (that is, they may revert to being more virulent).

- It was noted that unlike in other age groups, there did not appear to be a reduction in hospitalisation risk for Omicron compared with Delta in younger children (under 10 years old) though there was no indication of an increase in serious disease. For the small number of children who did attend hospital, the length of stay was observed to be typically short and where children stayed overnight it was often to allow for screening for other infections. It was noted that COVID-19 continues to account for a small minority of paediatric activity and paediatric intensive care occupancy has not changed significantly. It was stated that the relative risk of hospital admission for children could be estimated with more confidence when more data become available.
- The **Northern Ireland** Department of Health published an updated report on modelling the COVID-19 epidemic on 11 January 2022.⁽⁴⁹⁾ The following points were noted regarding risk and impact:
 - The newly adopted testing strategy, which involves the use of less sensitive lateral flow tests without the requirement for a confirmatory PCR test, will require approximately ten days to reach a new case baseline. In the interim, case numbers are not a reliable indicator of changes in community transmission of the virus or COVID-19 prevalence.
 - Based on previous modelling, it was estimated that Northern Ireland is at, or around, the peak in terms of case numbers for the Omicron wave at present, with current data supporting this position.
- On 12 January, the **NIPH** published an updated risk assessment and modelling report on the impact of the Omicron variant in Norway.^(6, 7) The NIPH estimated that the Omicron variant would result in a significant wave of infection between January and March. However the scale and consequence of this wave were uncertain at the time of the report. It was noted that the risk and disease burden depends on the combination of transmissibility and disease severity.
 - All modelling scenarios estimated that there would be a large wave of infections (ranging between 25,000 and 90,000 daily cases) with the peak occurring between mid-January and mid-February. The modelling suggested that this would be followed by an increase in hospitalisations

ranging between 100 to 400 daily admissions, peaking in late January or early February, resulting in between 500 and 2,500 concurrently hospitalised patients, and between 25 and 150 patients concurrently requiring ventilation. In alternative scenarios it was assumed that the risk of hospitalisation due to Omicron is lowered by 70% (instead of 50% in the base case scenario) compared with Delta, leading to a significantly lower burden on the healthcare system, with approximately 200 fewer hospitalisations per day at peak in the worst-case scenario. In the more-optimistic scenarios, in terms of absolute numbers the peak of hospitalisations was estimated to be comparable to the wave caused by the Delta variant in December 2021.⁽⁶⁾ It was noted that early removal of measures would lead to a larger wave, while stronger measures over time would lead to a smaller wave, but the wave would return once the measures are removed.

- It was noted that it would not be possible to stop the Omicron wave, but it may be possible to flatten the curve to avoid overwhelming the healthcare system and to minimise illness in society as a whole. It was stated that the aim of measures is to curb the epidemic with the fewest possible interventions.⁽⁷⁾
- In their latest risk assessment (published on 5 January 2022), the **SSI** of Denmark assessed that as Omicron was the dominant variant, there was a continued high risk of significant further increases in cases and hospital admissions over the next few weeks.⁽⁵⁰⁾ COVID-19 cases were projected to peak at the end of January and hospitalisations in early February.
 - The SSI, in their 13 January 2022 epidemiological trends report,⁽⁵¹⁾ concluded that overall, the epidemic was growing in Denmark, but a decline in test positivity was observed despite rising test activity. A small decrease in the number of admissions and a stabilisation in the number in intensive care was noted, despite the high infection rates of recent weeks. It was stated that, at the time of the report, the epidemic was being driven solely by Omicron, and the decrease seen in admissions may be due to decreasing infections with the Delta variant.

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