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EVIDENCE BRIEF

# COVID-19 Variant of Concern Omicron (B.1.1.529): Risk Assessment, February 23, 2022

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## Key Messages

- Current reporting of confirmed SARS-CoV-2 cases in some jurisdictions, including Ontario, is an underestimate of the true epidemiology of infections due to changes to polymerase chain reaction (PCR) testing eligibility. Rapid antigen tests (RATs) can be used in the community for diagnostic testing purposes, but there is growing evidence regarding the limitations of RATs.

- Three doses of a COVID-19 vaccine provides greater protection from severe outcomes of Omicron variant infection compared to two doses. Evidence continues to suggest third dose effectiveness against symptomatic infection wanes at 10, 16 and 24 weeks, but the duration of protection against severe disease is longer. There is early evidence that exposure to Omicron antigens, whether through infection or an Omicron-targeted vaccine, may not elicit strong neutralizing antibodies against other SARS-CoV-2 variants.

- Most of the evidence indicates that infection with the Omicron variant causes less severe disease compared to the Delta variant; however, there is increasing evidence that Omicron infections can still be severe in older age groups, in particular among older people with comorbidities. Despite evidence that Omicron causes less severe disease than Delta, due to increased transmissibility of Omicron, the absolute number of severe cases during the Omicron wave has strained health system capacity and critical infrastructure in many jurisdictions, but to varying degrees. At this time, there is insufficient data to comment on Omicron hospitalization outcomes, mortality, or long-term COVID-19 outcomes.

- The current risk of Omicron transmission in Ontario is high, with a low degree of uncertainty. The risk of reinfection and breakthrough infection (after two doses of Pfizer, Moderna, AstraZeneca, or a heterologous combination) in Ontario is high with a low degree of uncertainty. The risk of severe disease, particularly amongst unvaccinated individuals, is moderate with a low degree of uncertainty. The risks to testing and surveillance are moderate with a low degree of uncertainty. The overall risk assessment may change as new evidence emerges.

# Issue and Research Question

Since its identification on November 8, 2021 in South Africa,[1] Omicron has become the dominant severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variant in many countries. Since the last report on February 9, 2022,[2] more evidence has emerged of Omicron's transmissibility, immune evasion, and disease severity. This evidence brief updates the Public Health Ontario (PHO) report from February 9, 2022, and summarizes available information and evidence on the Omicron variant of concern (VOC) relevant to the risk in Ontario up to February 22, 2022. Data from Ontario was available up to February 23, 2022. The SARS-CoV-2 Omicron sub lineage BA.2 is out of scope for this Risk Assessment and will only be addressed when relevant to general Omicron B.1.1.529 literature or BA.1.

# Methods

PHO Library Services conducted daily searches of primary and preprint literature using the MEDLINE database (search strategies available upon request). In addition, PHO performed grey literature searches daily using various news feeds and custom search engines. English-language peer-reviewed and non-peer-reviewed (preprint) records that described COVID-19 variants were included.

# Main Findings

# Genomics

The last PHO Omicron Risk Assessment included a brief overview of hypotheses regarding the origins of the Omicron variant,[2] including a role for animal reservoirs. A recent study reported the identification of Omicron infection in free-living white-tailed deer in New York State.[3] Of the 131 white-tailed deer opportunistically sampled on Staten Island between December 2021 and January 2022, 19 (14.5%; 95% CI: 0.10–0.22) were positive for SARS-CoV-2 antibodies. Phylogenetic analyses revealed the deer Omicron sequences to be clustered closely with recently reported Omicron sequences from infected humans in New York City and elsewhere. The authors conclude that comprehensive surveillance of animals susceptible to SARS-CoV-2 infection is urgently needed to identify, track and understand human-to-animal-to-human spillovers/spillbacks.

# Epidemiology

In Ontario, Canada:

- As of February 22, 2022, whole genome sequencing (WGS) from surveillance testing across Canada reported that of SARS-CoV-2 samples collected the week of January 30, 2022, 98.8% were Omicron (33.2% BA.1, 53.9% BA1.1, 11.7% BA.2), but data were still accumulating.[4] On February 22, 2022, Canada reported 1,654 new cases, 5 new deaths, 121,528 active cases, and the daily percent positivity (over the previous 7 days) was 12%, all of which are lower than two weeks prior. The Public Health Agency of Canada (PHAC) notes that due to changes in COVID-19 testing policies in many jurisdictions starting in late December 2021, case counts will underestimate the total burden of disease.

- In Ontario, on December 20, 2021, 73.3% of samples tested at the PHO laboratory exhibited s-gene target failure (SGTF), indicating that Omicron was the dominant circulating variant.[5] The PHO laboratory discontinued SGTF testing on December 30, 2021. Due to changes in the eligibility criteria for PCR testing in Ontario effective December 31, 2021, reported confirmed case counts are an underestimate of the true number of individuals with SARS-CoV-2 infection.

- The Ontario 7-day confirmed case average was 838 on December 1, 2021, 12,078 on December 31, 2021, 4,390 on January 30, 2022, and 2,442 on February 14, 2022.[6]

- On December 31, 2021 (i.e., the day on which changes to the eligibility criteria for PCR testing took effect), the percent positivity was 34.3%.[7] On January 15, 2022, the percent positivity was 22.7%, on January 31 it was 16.2%, and on February 18 it was 11.8%.

- As of February 21, 2022, there were 101 ongoing outbreaks in long-term care homes, 80 in retirement homes, 103 in congregate living settings, 39 in hospitals, and 12 workplace outbreaks.[8]

Notable epidemiological trends from select jurisdictions are:

- The European Centre for Disease Prevention and Control surveillance report for the week ending February 13, 2022 reported that the case notification rate has been decreasing for two weeks, however, 15 countries reported increasing trends compared to the previous week among people aged 65 years and above, which could result in increases in severe disease in the coming weeks.[9] The 14-day death rate was 54.7 deaths per million population and has been stable for 12 weeks. Of 27 countries with hospitalization and intensive care unit (ICU) data, 14 reported an increasing trend in at least one of these indicators compared to the previous week.

- According to modelling projections, the United States (US) Centers for Disease Control and Prevention (CDC) estimated that for the week ending February 19, 2022, 100% of SARS-CoV-2 cases were Omicron[10] (75.6% BA.1.1, 20.6% B.1.1.529, 3.8% BA.2). As of February 16, 2022, the 7-day moving average of daily new cases (121,665) decreased -43.0% compared with the previous 7-day moving average (213,625).[11] The 7-day daily average hospitalizations from February 9 to February 15, 2022, was 8,642, which is an -28.8% decrease from the prior 7-day average (12,142) from February 2 to February 8, 2022.

- The United Kingdom (UK) sequencing data up to February 7, 2022, indicated 95.4% of SARS-CoV-2 sequences were BA.1, 4.1% were BA.2 and 0.5% were other lineages.[12]

    - Between February 16 and 22, 2022, there were 304,204 confirmed COVID-19 cases, which is a decrease of -17.5% compared to the previous 7 days.[13] Between February 12 and February 18, 2022, 8,326 individuals went into hospital with COVID-19, which is a decrease of -9.8% compared to the previous 7 days.

    - As of February 18, 2022, the reproduction number (R) for England ranged from 0.8 to 1.0 and the growth rate range for England was -4% to -1% per day.[14]

        - The hospitalization rate for COVID-19 in England was at 11.04 per 100,000 in week 6 compared to 13.59 per 100,000 in the previous week.[15] In week 6, the weekly ICU or high dependency unit (HDU) admission rate was at 0.31 per 100,000 compared to 0.48 per 100,000 in the previous week. Between February 16 and 22 February 2022, there were 976 deaths within 28 days of a positive coronavirus test, which is a decrease of -16.1% compared to the previous 7 days.[13]

- Data from the Our World in Data website collected on February 22, 2022 indicated Denmark's 7-day rolling average of new cases per million people increased from 722 on November 30, 2021 to a peak of 7,970 on February 13, 2022, and was 6,159 on February 20, 2022.[16]

- On February 22, 2022, South Africa reported 2,334 new COVID-19 cases and an 7.3% positivity rate, which are a decreased from two weeks before.[17]

# Transmissibility

Modelling, *in vivo*, *in vitro* and *in-silico* analyses support epidemiological findings that Omicron is more transmissible and suggest potential mechanisms. It remains unclear to what extent the increased transmission of Omicron is due to inherent characteristics of the virus (i.e., enhanced ability to infect cells, tissue tropism) or due to immune evasion.

- The human angiotensin-converting enzyme 2 (hACE2) receptor is used by SARS-CoV-2 to enter host cells; therefore, mutations that alter binding affinity or stability or tissue tropism (e.g., faster replication in human bronchi as opposed to lungs) could impact infectivity and transmission. Since the last PHO Risk Assessment, more studies have reported Omicron to have enhanced ACE binding, compared to wildtype or other VOCs.[18,19] For example, an extensively validated artificial intelligence (AI) model estimated that Omicron may be more than 10 times more contagious than wildtype SARS-CoV-2 or 2.8 times as infectious as Delta.[19] Additional studies have reported evidence of mechanisms of immune evasion, including reduced antigenicity of the Spike protein,[20] and a role for electrostatic charges in destabilizing antibody binding.[18]

- Two studies described Omicron viral load and potential transmission. One study conducted at a drive-through testing centre in Toulouse, France compared the nasopharyngeal (NP) viral load of Delta (n=975) and Omicron (n=1578) infections.[21] The NP viral loads of Omicron cases were lower than those of Delta cases (p=0.04), however, after adjusting for age, sex, symptoms and vaccination status, NP viral loads of Delta and Omicron cases were not significantly different. The authors conclude that their findings show the Omicron variant is more contagious primarily because of vaccine escape as opposed to greater virus shedding in the nasopharynx. Another study collected aerosol samples from COVID-19 patients infected with Delta (n= 4) or Omicron (n = 5) while doing various respiratory activities.[22] SARS-CoV-2 RNA was consistently detectable in respiratory samples of all Omicron patients despite them being fully vaccinated and mostly asymptomatic, as compared to the Delta patients (only 2/4 participants had detectable RNA in respiratory samples). The greatest viral loads were generated during singing and talking without a mask. Fine aerosols (≤ 5 μm) exhibited higher positivity (77.8% vs 44.4%) and greater viral loads (median 774.6 vs 354.2 copies, summating all respiratory activities) compared to coarse aerosol (> 5 μm). The authors conclude Omicron respiratory aerosols present a risk of transmission.

- A recent summary of CDC genomic surveillance data sources from June 2021 to January 2022, reported that the Omicron variant proportion had an estimated initial doubling time of 3.2 days (95% CI = 3.1–3.4 days), which was faster than Delta (7.2 days; 95% CI = 7.0–7.4 days), Alpha (11.0 days; 95% CI = 8.3–16.1 days), Gamma (13.1 days; 95% CI = 12.0–14.3 days), and Mu (14.7 days; 95% CI = 13.8–15.7 days).[23] They also estimate Omicron rose from 1% to 99% of infections nationally in 6 weeks, compared with 18 weeks for Delta.

- A study described an increase in hospital-onset SARS-CoV-2 cases in a large US hospital at the same time as an Omicron surge.[24] In the study, the use of a cluster response protocol that included N95 respirators for all patient care on affected units regardless of patients' SARS CoV-2 status, testing all uninfected patients daily, and limiting rooms to one patient whenever possible, rapidly controlled the outbreak. Prior to the study, the SARS-CoV-2 control program included PCR testing all patients on admission, retesting all inpatients 72 hours later, universal use of surgical masks (employees, patients, visitors), eye protection, restricting visitors to 2/day, an employee vaccination mandate, symptom attestations before each shift, contact tracing and exposure notifications, and onsite, on-demand SARS-CoV-2 PCR testing for employees. Prior to the Omicron surge, this policy was effective. The incidence of hospital-onset cases rose from 0/23,818 patients-days in November (0.0 per 1000 patient-days), to 12/24,174 patient-days in December (0.5 per 1000 patient days), to 33/11,165 patient-days January 1-15(3.0 per 1000 patient-days), which paralleled rates of community transmission. Contact tracing during the outbreak revealed that of 45 cases, 22 received care from healthcare workers with undiagnosed SARS-CoV-2, 5 were roomed with patients with undiagnosed SARS-CoV-2, 1 had a visitor with undiagnosed SARS-CoV-2, and the remaining 17 patients had no potential source identified. There were two unit-based clusters that started January 1 and 2. Upon initiation of the revised cluster response protocol, no additional cases were identified in the cluster in the ten days that followed, even with daily testing. A report of an Omicron outbreak in South Korea also indicated high transmissibility, with the following estimated the secondary attack rates for a total of 11 clusters within three weeks: family gathering, 83.3%; church, 80%; households, 58.9%; restaurants, 46.8%; kindergarten 1, 39.2%; and kindergarten, 2, 24.0%.[25]

# Diagnostics

Although most current molecular tests for SARS-CoV-2 are expected to be able to detect Omicron B.1.1.529, there is strong evidence of variable sensitivity, optimal detection windows and optimal specimen site for rapid antigen tests (RATs), as described in previous PHO Risk Assessments,[2,26-28] and elsewhere.[29] Two recent primary studies are highlighted below.

- Mid-turbinate (MT) nasal swabs, oropharyngeal (OP) swabs and saliva samples were analyzed to quantify antigen and molecular test performance during an Omicron wave.[30] The study used a familial cohort and a cross-sectional cohort, evaluating the impact of symptom duration and vaccination status on test performance at each site. The familial cohort (n=3) showed consistently higher antigen concentrations and lower Ct values in anterior nares (AN) samples as compared to paired OP and saliva samples at all timepoints (8-10 samples over 8-11 days, starting the first day after symptom onset). Among the cross-sectional cohort participants, RT-PCR was performed on 54 MT, 45 OP, and 51 saliva specimens and nucleocapsid antigen assay was performed on 52 MT, 43 OP and 50 saliva specimens. The positive percent agreement (PPA) [95% CI] for RT-PCR was 66.7 [54.1–79.2], 82.2 [71.1–93.4], and 72.5 [60.3–84.8] in MT, OP and saliva specimens, respectively. The antigen detection exhibited 46.2 [32.6–59.7], 51.2 [36.2–66.1], and 72.0 [59.6–84.4] PPA at a cut-off of 3 pg/mL. A composite result of MT or OP specimens, which was calculated only for individuals who had both specimens analyzed, showed 86.7 [76.7–96.6] for RT-PCR and 59.5 [44.7–74.4] for antigen detection. Distribution of Ct values showed no significant differences when comparing any two sample types across the cohort (MT vs OP $p = 0.32$, SA vs OP $p = 0.26$, MT vs SA, $p = 0.8$). Antigen concentrations and Ct values from the three specimen sites showed poor absolute agreement (interclass correlation [95% CI] 0.12 [0.07–0.18] and 0.11 [0.07–0.15], respectively). There was no significant difference between sample types collected at different days since symptom onset, based on Ct or antigen distribution (rank-sum test comparing OP and MT, OP and saliva, and MT and saliva, all p values > 0.05). The authors conclude that antigen and RNA tests have similar enough kinetics and diagnostic ability in MT, OP and saliva samples across the duration of symptomatic disease, and therefore advise against changes to recommended testing practices (e.g., samples from combined sites) at this time. This is in contrast to some reports described in previous PHO Risk Assessments.[2,26-28]

- A quality improvement study was conducted to determine the suitability of combined oropharyngeal/nares (OPN) and nasopharyngeal (NP) swab sampling.[31] Participants (n=392) were mostly symptomatic or a close contact of a known case. Using nucleic acid amplification testing (NAAT), comparing paired specimens from participants, the sensitivity of NP swabs was 89.1% (95% CI, 78.8-94.9), while that of OPN was 98.4% (95% CI: 90.9->99.9) (p-value 0.052). The authors conclude that both NP and combined OPN swabs detected the Omicron variant with similar sensitivity by NAAT, which supports the continued use of either swab collection for SARS-CoV-2 molecular detection.

# Disease Severity

There remain limitations with the Omicron severity literature (e.g., lag time to observe hospitalizations and mortality, how cases hospitalized due to Omicron are identified, varying levels of immunity across study populations);[32] however, most of the evidence suggests that Omicron causes less severe disease than Delta. There remains insufficient data to comment on hospitalization outcomes, including progression of severity of illness, complications, and mortality. Select studies since the last PHO Omicron Risk Assessment are highlighted below.

- Using a combination of specimens and health administrative data (n=40,991), a study from the US Houston Methodist healthcare system compared Omicron patients to patients infected with other VOCs, based on time periods when each VOC was dominant.[33] Of note, Omicron patients were also significantly younger than Alpha and Delta patients (p<0.0001), and a significantly larger proportion of Omicron patients were vaccinated than Alpha or Delta patients (p<0.0001). In terms of severity, Omicron patients were hospitalized significantly less frequently than Alpha patients (884/4,468, 19.8% vs 1717/3149, 54.6%, respectively, p<0.0001, odds ratio: 0.205 [95% CI, 0.185-0.227] and Delta patients (6779/15728, 43.1%, p<0.0001, odds ratio: 0.326 [95% CI, 0.301-0.353]). Omicron patients had significantly shorter median hospital length of stay compared to Alpha patients (3.2 vs 5.1 days, respectively, p<0.0001) and Delta patients (3.2 vs 5.4 days, p<0.0001).

- A retrospective analysis of health administrative data from an emergency department (ED) in the US compared reports of croup from the Delta dominant period (n=401) and the initial phase of the Omicron surge (n=107).[34] Patients who presented with croup during the Omicron surge were more likely to test positive for COVID-19 (48.2% vs 2.8%, p<0.0001). No differences were observed in presenting age, rate of admission, rate of return to the ED within 72 hours, or admission among those who returned within 72 hours, between the Delta and Omicron periods. During the Omicron surge, the incidence of croup almost doubled as compared to the rate in previous months. Of note, at the same time, there was a decreased in the number of cases of parainfluenza virus.

- A study conducted at a drive-through testing centre in Toulouse, France, reported that Omicron cases (n=1,578) had more mild symptoms (63.2% [60.7%-79.8%]) than Delta cases (n=975) (51.8% [48.6%-55.0%]; p<0.01).[21] Omicron cases were more often symptomatic (OR=1.24; p<0.01), more commonly vaccinated (OR=1.48; p<0.01), and younger (OR=0.99; p<0.01) than Delta cases.

- A case-control study of 5,728 adults hospitalized with COVID-19 and 5,962 controls hospitalized without COVID-19, in 21 hospitals across the US, compared outcomes by variants based on either WGS or dominant circulating VOC at the time.[35] Vaccine effectiveness (VE) of mRNA vaccines against hospitalization were: 85% (95% CI: 82 to 88%) for 2 vaccine doses against Alpha; 85% (95% CI: 83 to 87%) for 2 doses against Delta; 94% (95% CI: 92 to 95%) for 3 doses against Delta; 65% (95% CI: 51 to 75%) for 2 doses against Omicron; and 86% (95% CI: 77 to 91%) for 3 doses against Omicron. In terms of severity based on the World Health Organization (WHO) Clinical Progression Scale, severity was higher for Delta than Alpha (adjusted proportional odds ratio [aPOR] 1.28, 95%CI: 1.11-1.46), and lower for Omicron than Delta (aPOR 0.61, 95% CI: 0.49-0.77). Severity was lower for vaccinated cases compared to unvaccinated cases for each variant, including Alpha (aPOR 0.33, 95%CI: 0.23-0.49), Delta (aPOR 0.44, 95%CI: 0.37-0.51), and Omicron (aPOR 0.61, 95%CI: 0.44-0.85). Including both vaccinated and unvaccinated patients, a total of 582/5,413 (11%) COVID-19 patients died within 28 days of hospitalization, with breakdown by VOC as follows: 81/1,060 (8%) in the Alpha group, 461/3,788 (12%) in the Delta group, and 40/565 (7%) in the Omicron group. As compared with the 424 unvaccinated COVID-19 patients who died, 158 vaccinated patients who died were older (median 72 vs 61 years; p<0.001), more likely to be immunocompromised (41% versus 13%; p<0.001), had more categories of chronic medical conditions (median 3 versus 2; p<0.001), and had more prescribed medications before hospital admission (median 10 versus 5; p<0.001). The 2 or three dose effectiveness of mRNA vaccination against progression to invasive mechanical ventilation (IMV) or death was 76% (95%CI: 53-88%) for Alpha, 44% (95%CI: 32-54%) for Delta, and 46% (95%CI: 12-67%) for Omicron.

# VE

Since the last PHO Risk Assessment,[2] more evidence has emerged demonstrating that two doses of COVID-19 vaccines are less effective at preventing Omicron breakthrough infections compared to other VOCs and 'wild-type' SARS-CoV-2, and a third COVID-19 vaccine dose increases protection against symptomatic Omicron infection and severe disease. A few VE studies are described below.

## Epidemiological Studies

- An open-label, clinical intervention trial of fourth doses of Pfizer (n=154) or Moderna (n=120) was conducted in triple-vaccinated (at least 4 months earlier) healthcare workers (1,050 eligible) and 426 age-matched controls, after the emergence of Omicron.[36] Of note, five months after the third dose (pre-dose 4), anti-RBD IgG titers were 6-fold lower than one month after receiving the third dose (peak post-dose-3 titers) in all three groups, but they were also 5-fold higher than titers measured five months after the second dose (pre-dose 3). Within 1 to 3 weeks of receiving either of the vaccines as a fourth dose, anti-RBD IgG titers increased 9- to 10-fold, reaching titers a little higher than the first month after the third dose. The anti-RBD-IgG levels of the control group continued to wane. The pre-dose-4 neutralizing antibody titers (4-5 months after the third dose) had a GMT of 355 (95%CI 270-467) and 276 (95%CI 210-363) for Pfizer and Moderna, respectively. Of the participants assessed for T-cell activation, among Pfizer recipients, the proportion of responders increased from 50% to 60% on day 14, but the mean number of T cells activated by the spike protein did not change (131±27 to 132±32). Among the Moderna recipients, the proportion of responders increased from 61% to 87%. Of the samples that were assessed for direct neutralization of Omicron as compared to Delta and wild-type strain before the fourth dose (4-5 months after the third dose), for both vaccines and at all time-points, neutralization of Omicron was 10-fold less than that of wild-type and 4-7-fold lower than Delta. Recipients of Pfizer reached a 10.7-fold increased neutralization of Omicron by day 14, and Moderna recipients reached a total 7.2-fold increase by day 14. After adjusting for period of exposure and age-group, the vaccine efficacy was 30% (95%CI: -9-55%) for Pfizer and 11% (95%CI: -43-44%) for Moderna. For symptomatic disease, the vaccine efficacies were 43% (95%CI: 7-65%) and 31% (95% CI: -18 to 60%), respectively.

- A study in mice evaluated the antibody responses and protective activity against Omicron virus of a preclinical version of the Moderna vaccine, mRNA-1273, or an Omicron-targeted vaccine, mRNA-1273.529, designed with sequences from wildtype or B.1.1.529 spike genes, respectively.[37] The study characterized the functional antibody responses by measuring the inhibitory effects of serum on SARS-CoV-2 infectivity using a focus-reduction neutralization test, and evaluated the protective activity of the mRNA-1273 vaccines against B.1.1.529 challenge in mice. The mouse studies revealed that the Omicron-targeted mRNA-1273-529 vaccine strongly induced neutralizing antibodies against Omicron; but the neutralizing antibody titers against Washington-1 (WA1)/2020 D614G, B.1.351, and B.1.617.2 strains were much lower. This could suggest an Omicron-specific vaccine may function as a suitable booster against Omicron but may not boost protection against other variants. Another study described an Omicron-specific lipid nanoparticle (LNP) mRNA vaccine candidate that was tested for antibody induction in animals, both alone and as a booster to an existing mRNA vaccine designed against WA-1, an ancestral reference virus .[38] The booster version induced potent antibody response against the Omicron variant, and also elicited broader antibody responses against WA-1 and Delta variants.

- A CDC study investigated case rates, death rates and incidence rate ratios (IRRs) among unvaccinated and fully vaccinated adults by receipt of booster doses during pre-Delta (April–May 2021), Delta emergence (June 2021), Delta predominance (July–November 2021), and Omicron emergence (December 2021) periods in the US.[39] In the Omicron emergent period, case IRRs decreased to 4.9 for fully vaccinated, boosted individuals and 2.8 for those without booster doses, relative to October–November 2021. The age-standardized IRR for cases in unvaccinated compared to fully vaccinated individuals was 13.9 during April to May 2021, declining to 8.7 during Delta emergence, 5.1 during Delta predominance, and 3.1 during Omicron emergence. Rates of cases were lowest among fully vaccinated, boosted individuals as compared to fully vaccinated individuals without a booster dose, and much lower than among unvaccinated individuals during October–November (25.0, 87.7, and 347.8 per 100,000 population, respectively) and the Omicron emergent period (148.6, 254.8, and 725.6 per 100,000 population, respectively). Age-standardized case IRRs among unvaccinated persons compared with persons with a booster dose declined from 13.9 during October–November to 4.9 during the Omicron emergent period, which translated to a potential decrease in crude VE for infection from 93% to 80%, respectively. Comparing unvaccinated individuals with fully vaccinated, unboosted individuals, age-standardized case IRRs during October–November and December were 4.0 and 2.8 respectively, which translates to decreases in VE from 75% to 64%. From October to November, age-standardized IRRs for deaths among unvaccinated individuals were 53.2 compared with those in fully vaccinated, boosted individuals and 12.7 as compared to those without a booster. The authors also found that booster doses provided the most added benefit for persons aged ≥65 years.

- A study was conducted of total and neutralizing antibodies against WA-1 and Beta, Delta and Omicron VOCs in a longitudinal cohort of healthcare workers (n=1,353) within 14-44 days post-dose 2 of an mRNA SARS-CoV-2 vaccine (Timepoint 1), or at least 8 months post-dose 2 (Timepoint 2), or within 14-44 days following an mRNA booster (Timepoint 3).[40] The level of antibodies at Timepoint 1 waned to lower levels at Timepoint 2, and then increased after a booster to much higher levels at Timepoint 3. Of the Timepoint 3 samples tested, 94% exhibited spike IgG assay saturation as compared to 59% in Timepoint 1. At Timepoint 2, there was little neutralizing antibody to Beta and Delta, and none to Omicron (titer <20). The authors concluded that neutralizing capacity to any VOC tested is lost by 8-months post two-dose vaccination series, and an mRNA booster dose provides greater quantity and quality of antibodies compared to a two-dose regimen and is critical to provide any protection against Omicron. An additional but small study, also reported lower neutralizing titers against Omicron B.1.1.529.[41]

# Breakthrough Infections and Reinfections

As more individuals in a population become vaccinated, a greater proportion of SARS-CoV-2 infections will occur in vaccinated individuals. However, this does not mean that vaccinated individuals are more likely to get infected. Since the last PHO Risk Assessment,[2] more evidence has emerged characterizing reinfections and breakthrough infections caused by Omicron.[21] Some studies are highlighted below

- Using a combination of specimens and health administrative data (n=40,991), a study from the US compared Omicron patients to patients infected with other VOCs, based on time periods when each VOC was dominant.[33] In terms of VE, 2,497 of the 4,468 Omicron patients (55.9%) for whom there was WGS data, met the CDC definition of vaccine break-through cases. A greater percentage of breakthrough cases were caused by Omicron (55.9% compared with 3.2% and 24.3% for Alpha and Delta VOCs, respectively). There were 711 Omicron cases that had received a third mRNA vaccine doses.

- A small study compared the humoral responses of 20 unvaccinated and 7 vaccinated (Johnson & Johnson [n=2] or two doses Pfizer [n=5]) Omicron cases to determine if Omicron infection results in cross-reactive humoral responses to other VOCs.[42] The study looked at binding, antibody-dependent cellular cytotoxicity, antibody-dependent cellular phagocytosis and neutralization. In unvaccinated cases, Fc effector function and binding antibodies were at comparable levels for Omicron relative to other VOCs (though reduced), but neutralization against VOCs showed a 20 to 43-fold reduction in titer compared to Omicron neutralization. In contrast, Omicron cases that were previously vaccinated had improved cross-neutralization of VOCs, with titers exceeding 1:2,900. In addition, previously vaccinated Omicron cases exhibited substantially higher binding against Omicron than unvaccinated individuals (GMT of 2.92 versus 1.92). The authors suggest this has important implications for the vulnerability of unvaccinated Omicron-infected individuals to reinfection by circulating and emerging VOCs. Their findings also raise the question of whether Omicron-specific vaccines would provide sufficient priming in SARS-CoV-2 naïve individuals, similar to the two mouse studies described earlier.[37,38]

# Measures in Response to Omicron

This section was informed by scanning government websites and searches in the Google search engine for literature related to Omicron, public health measures, and vaccination programming. The following jurisdictions were searched on February 22, 2022: Denmark, England, Finland, France, Germany, Ireland, Israel, Italy, Netherlands, Norway, Portugal, and the US (New York State and California). For more detail regarding the public health measures in these jurisdictions, please see to the recent environmental scan, 'Public Health Measures and COVID-19 Epidemiology in Select Jurisdictions (Current up to February 2, 2022)'.[43]

- All included jurisdictions implemented public health measures in response to the emergence of Omicron. In January, 2022, due to reported stabilizing hospitalizations, many jurisdictions eased or lifted public health measures, while at the same time, encouraged vaccination.[43] Since the last risk assessment,[2] jurisdictions continued to lift public health measures including outdoor and/or indoor mask mandates,[44-49] capacity and/or gathering limits,[46,50-53] setting-specific closures,[53-55] remote work mandates,[46,56,57] and proof of vaccination.[51,53,56] Currently, there is variation in the status of implemented public health measures across jurisdictions. Largely, the remaining public health measures across the jurisdictions focus on high-risk settings rather than broad community measures.

# Ontario Risk Assessment

- The current risk of Omicron transmission in Ontario is high, with a low degree of uncertainty. The risk of reinfection and breakthrough infection in Ontario is high, with a low degree of uncertainty, while the risk of severe disease, particularly amongst unvaccinated individuals, is moderate, with a low degree of uncertainty. Changes to limit eligibility for molecular testing in Ontario were implemented as of December 31, 2021; these changes mean that reported cases of SARS-CoV-2 in Ontario are an underestimate of the true epidemiology of infections and have impacts on surveillance quality. The incidence of severe cases due to increased transmission is a threat to health system capacity.

- The overall risk assessment may change as new evidence emerges (see Table 1).

**Table 1. Risk Assessment for Omicron B.1.1.529**

| Issues | Risk Level | Degree of Uncertainty |
|---|---|---|
| Increased Transmissibility | High | Low |
| Disease Severity | Moderate | Low |
| COVID-19 Re-infection | High | Low |
| Lowered Vaccine Effectiveness/Breakthrough Infections | High | Low |
| Impacts on Testing | Moderate | Low |
| Impacts on Surveillance | Moderate | Low |

# Implications for Practice

The rapid increase of Omicron cases in Ontario in December and January and subsequent changes in eligibility for PCR testing have made it more challenging to interpret the epidemiology of SARS-CoV-2. New data sources are being identified and new models for projections are being generated, but it will take time to optimize these new tools. This presents a challenge to monitoring SARS-CoV-2 epidemiology in response to changes to public health measures, which is important for reducing the risk of surges as measures are lifted. Of note, differences in health system capacity across jurisdictions means the same changes in hospitalization rate may be met with different changes to public health measures, based on what is most suitable to a given jurisdictions health system and critical infrastructure capacities.

There remain unknowns related to the trajectory of Ontario's Omicron wave, which are important to consider in relation to a benefit and/or need for community-based public health measures. The emergence of the BA.2 sub lineage, for example, or other VOCs, introduces additional unknowns and therefore risks to anticipation of a decline in SARS-CoV-2 burden. A gradual approach to removal of public health measures across multiple settings can help mitigate risk of resurgence and health system impacts. Public health measures (e.g., masking, capacity limits), ongoing efforts to vaccinate all eligible individuals and accelerated booster vaccinations are important to control the transmission of Omicron, reduce population morbidity and mortality, and address impacts to the health system.

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