

# Administration of COVID-19 booster doses: Recommendations for winter and spring 2023

## SCIENTIFIC ADVICE INTERIM

Comité sur l'immunisation du Québec

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### Highlights

- ▶ This document presents the recommendations of the Comité sur l'immunisation du Québec (CIQ) regarding the direction the COVID-19 vaccination program should take in the winter and spring of 2023 to efficiently achieve its objectives.
- ▶ Since the beginning of the vaccination program, the primary objective has been the protection of the most vulnerable persons and the prevention of severe disease and death due to COVID-19.
- ▶ Vaccines against COVID-19 remain an essential tool given their effectiveness in preventing severe infections, primarily those leading to hospitalizations or death.
- ▶ Individuals with hybrid immunity, following a first episode of COVID-19 and the administration of at least 2 doses of mRNA vaccines, have strong protection against hospitalization due to COVID-19.
- ▶ Vaccinated individuals who have never been infected have less protection against hospitalization due to COVID-19 and this protection decreases over time.
- ▶ The greatest gain in terms of preventing hospitalizations and deaths will be achieved by ensuring vaccination of those at high risk of complications who have not yet been infected.
- ▶ **The CIQ recommends a booster dose of a COVID-19 vaccine for high-risk individuals who have not yet been infected and whose last dose was given at least 6 months previously, regardless of the vaccine product previously given.**
- ▶ As previously defined (<https://www.inspq.qc.ca/publications/3219-vaccination-influenza-covid-2022>), these high-risk individuals are residents of CHSLDs (long-term care facilities) or RPAs (private seniors' residences), persons aged 60 or older, persons aged 5 or older who are immunocompromised, on dialysis, or with chronic conditions at high risk of complications due to COVID-19, health care workers, pregnant women, and adults living in remote or isolated areas.

## Background and purpose of this interim opinion

At the beginning of the COVID-19 vaccination campaign, results from clinical studies showed that two doses of vaccine provided excellent protection against disease and hospitalization due to COVID-19(1). However, the large epidemic wave caused by the arrival of the Omicron variant in late 2021 led to a broad recommendation to administer a booster dose to all adults(2). This outbreak highlighted the reduced performance of the vaccines in preventing symptomatic COVID-19, while demonstrating that they continued to provide good protection against severe forms of the disease(3,4). The evolution of the Omicron variant into various subvariants, which were either more transmissible or able to evade vaccine immunity or post-infection immunity, caused a succession of epidemic waves in 2022. Because vaccine effectiveness against Omicron variants decreases over time, to reduce the impact of COVID-19 during the fall/winter 2022-23 season, the Comité sur l'immunisation du Québec (CIQ) recommended that an additional booster dose be administered to certain vulnerable groups as early as late summer in 2022(5).

This statement presents the CIQ's analysis and recommendations regarding the direction the COVID-19 vaccination program should take in 2023 to efficiently achieve its objectives.

## Objectives of the COVID-19 vaccination program

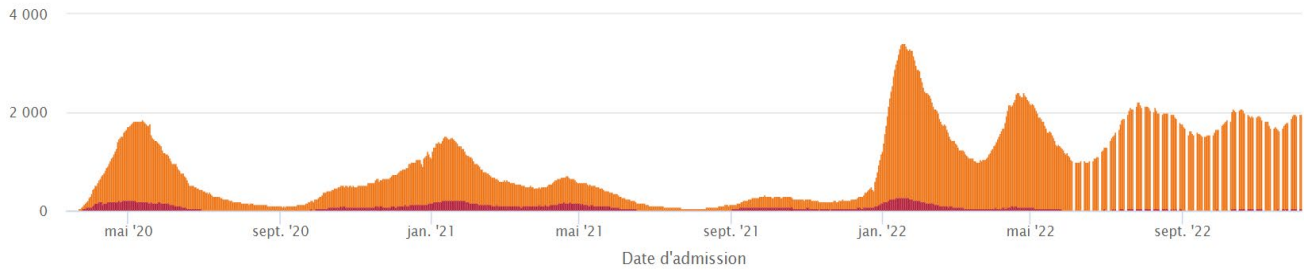
Since the beginning of the vaccination program, the primary objective has been the protection of the most vulnerable persons and the prevention of severe disease and death due to COVID-19(6). It is the CIQ's view that this objective remains relevant and achievable. This opinion paper will therefore focus on the vaccine strategy best suited to achieving this objective.

While theoretically, prevention of disease and absenteeism among health care workers and those providing services in long-term care facilities (CHSLDs), hospitals and in certain other settings with highly vulnerable individuals is a desirable objective, in practice it has unfortunately become unattainable, given the limited effectiveness of the vaccine in preventing non-severe SARS-CoV-2 infection and the rapid waning of this protection.

## Epidemiology of COVID-19

Between the beginning of the pandemic and the week of December 4, 2022, there were just over 77,000 COVID-19-related hospitalizations in Québec, of which approximately 9,000 were admitted to intensive care. During the fifth wave that coincided with the arrival of the Omicron BA.1 variant in late 2021, the number of incident hospitalizations reached all-time highs (Figure 1). This number remained high throughout the year with some increases during subsequent waves linked to the BA.2 and BA.4/5 subvariants. The BQ1 and BQ1.1 subvariants, which emerged in October 2022, progressed rapidly and accounted for more than 50% of the sequenced viruses by the end of November 2022.

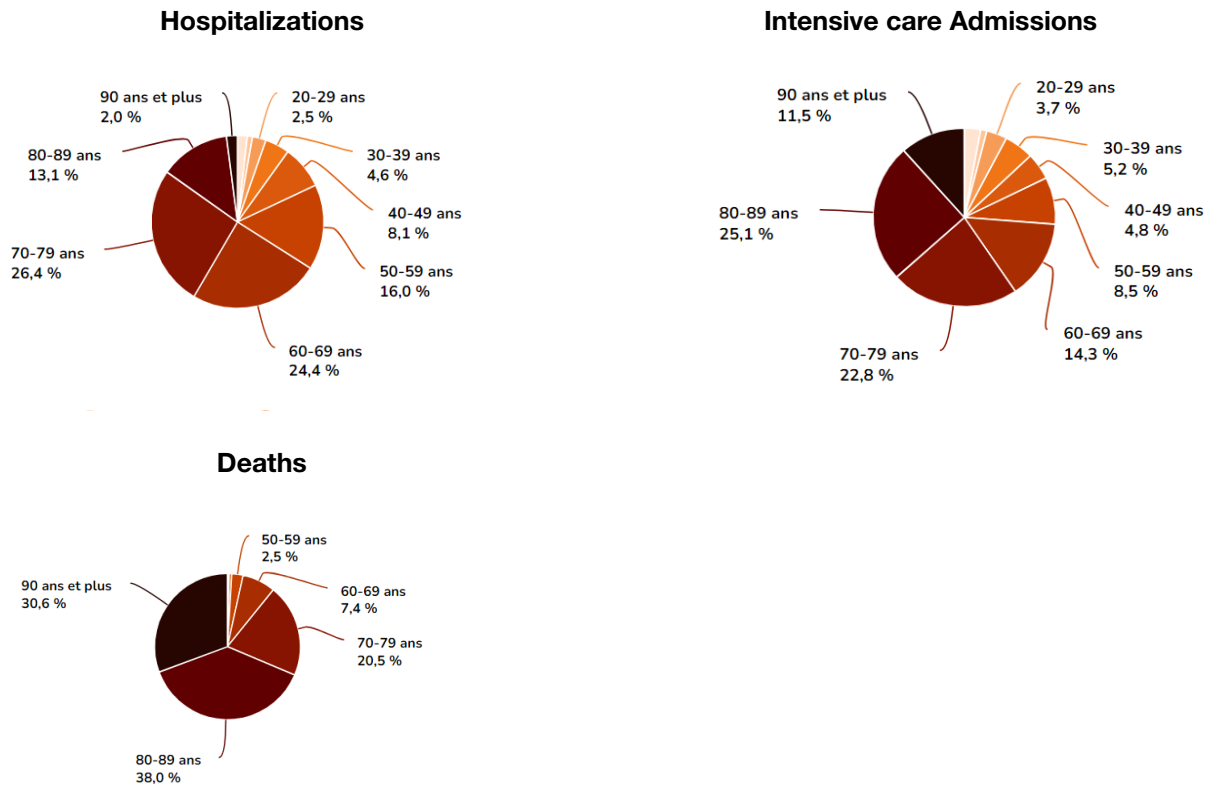
**Figure 1** Number of COVID-19-related incident hospitalizations in Québec, March 12, 2020 to December 6, 2022



Source: INSPQ, <https://www.inspq.qc.ca/covid-19/donnees>

Severe disease and deaths are primarily concentrated among persons aged 60 and older, who account for 66% of hospitalizations, 74% of intensive care admissions, and 96.5% of deaths (Figure 2). Since the beginning of 2022, the proportion of adults with at least one comorbidity has been 90% for hospitalizations, 85% for intensive care admissions, and 94% for deaths due to COVID-19 (Pierre-Luc Trépanier, personal communication, retrieved December 21, 2022).

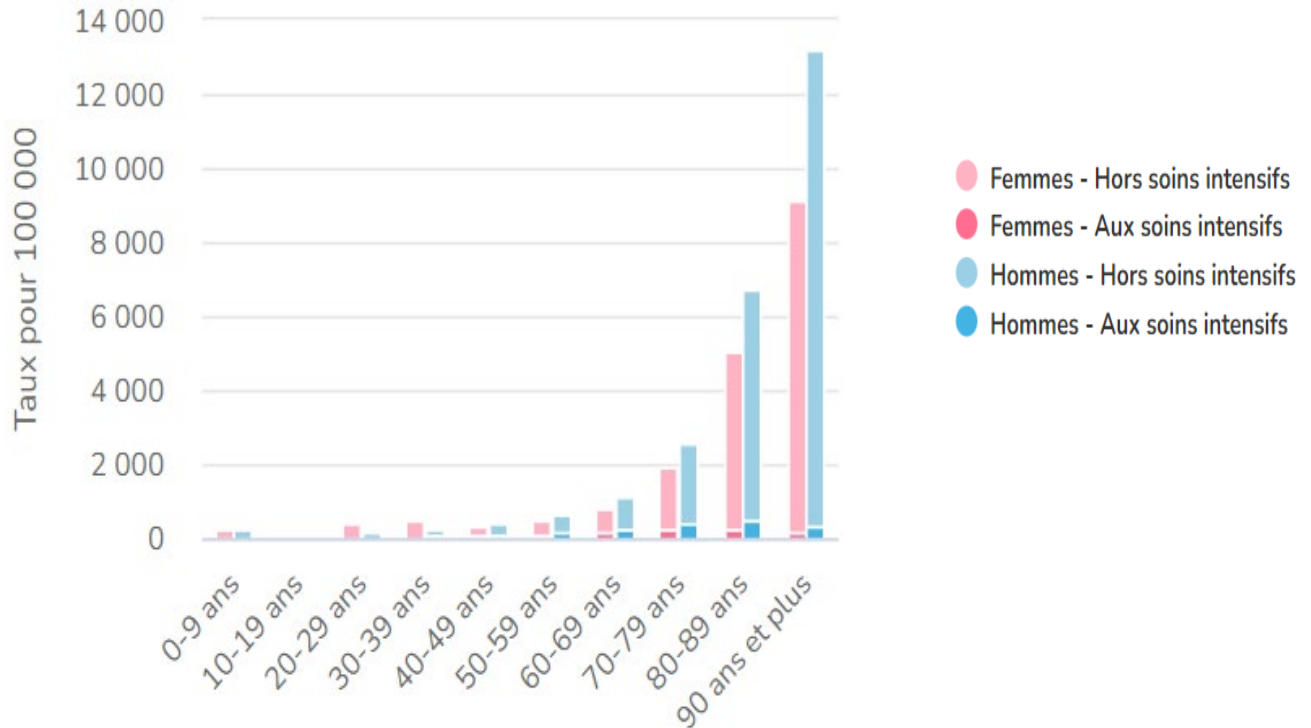
**Figure 2** Distribution of COVID-19-related hospitalizations, intensive care admissions, and deaths by age group from the start of the pandemic to December 4, 2022



Source: INSPQ <https://www.inspq.qc.ca/covid-19/donnees>

The risk for severe COVID-19 is higher in men than in women, in terms of standardized rates of hospitalization (936 vs 771 per 100,000), ICU admission (130 vs 73 per 100,000), and death (220 vs 151 per 100,000). Hospitalization rates are higher for men than for women starting at age 40 (Figure 3).

**Figure 3 COVID-19-related hospitalization rates by age and gender from the start of the pandemic to December 4, 2022**



Source: INSPQ <https://www.inspq.qc.ca/covid-19/donnees>

With the extensive transmission of SARS-CoV-2 linked to the Omicron variant and its subvariants, a very large proportion of the population has been infected since the beginning of the pandemic. Among Héma-Québec plasma donors, nearly 60% of donors aged 18 to 64 had serological evidence of an infection that occurred between December 2021 and August 2022 and approximately 30% of donors over 65 had been infected(7). Among blood donors in other Canadian provinces, 54% had serological evidence of prior infection in July 2022, including 71% in the 17-24 age group and 38% in the 60+ age group(8). In British Columbia, among those who had blood drawn for any health problem, 70% to 80% of children, 60% to 70% of adults aged 20 to 59, and just under 50% of adults aged 60 and older had serological evidence of prior infection(9). Among children aged 17 and younger in the greater Montréal region, 50% to 60% of those who visited the emergency department in the spring of 2022 had serological evidence of prior infection(10). These prior infections induce an immune response that protects against severe disease (refer to the section on post-infection and hybrid immunity).

SARS-CoV-2 is constantly evolving and each new epidemic wave since 2021 has coincided with the arrival of a new variant or subvariant. This is likely to continue to happen. These new variants or subvariants have genetic characteristics that make them either more contagious or better able to evade immune defences related to vaccination and/or prior infections.

## Post-COVID-19 syndrome or long COVID

Post-COVID-19 syndrome (PCS), or long COVID, refers to the persistence of COVID-19-related symptoms for several weeks or even months. The World Health Organization's clinical definition of PCS requires that symptoms persist for at least 12 weeks(11). According to the Canadian COVID-19 Antibody and Health Survey (CCAHS), conducted in the spring of 2022, 15% of adults having had a confirmed or suspected infection experienced long-term symptoms; almost half (47.3%) experienced symptoms for a year or longer and 21.3% reported that they often or always limited their daily activities(12). Because the CCAHS was conducted in the spring of 2022, individuals whose symptoms had persisted for 6 months or longer had been infected before the arrival of the Omicron variant. The main persistent symptoms reported included fatigue (72%), cough (39%), shortness of breath or difficulty breathing (39%), difficulty thinking or problem solving (33%), and general weakness (31%).

Numerous international studies have described the frequency of PCS and of all types of COVID-19 sequela(13). The exact frequency is difficult to estimate given the great variability of the populations studied, the definitions used, the methods of observation and the duration of follow-up. In general, PCS is more common among women than among men, more common among the elderly than among the young, and the risk increases with the severity of the initial illness. PCS has been studied mainly in relation to the original SARS-CoV-2 Wuhan strain and its early variants. The frequency of PCS varies according to the infecting strain and is reported to be two to four times lower with the Omicron variant than with the Delta variant(14).

Overall, vaccination prior to an initial COVID-19 infection appears to reduce the risk of PCS occurring with an initial COVID-19 episode by 17% to 35%(15–17) . The majority of studies indicate a protective effect after two vaccine doses, but there is considerable heterogeneity in the results due to the diversity of the populations studied and the methodologies used(15,17). Administering a vaccine to those already with PCS also appears to reduce the duration or severity of PCS by 17% (18). However, results were heterogeneous as to the extent of the effect, with the presence of information bias potentially leading to overestimation of the actual level of protection(15,18).

The primary impact of vaccination on PCS is not primarily from a reduction of its frequency or severity, but rather comes from the primary prevention of symptomatic and severe COVID-19 infections. Prior to the arrival of the Omicron variant, two doses of vaccine reduced the risk of hospitalization by more than 90% and the risk of symptomatic infection by 80%. Vaccine effectiveness has declined since the arrival of the Omicron variant and its sublineages, and the effect of vaccination on the risk of PCS occurring with an initial infection by Omicron or with a reinfection is not well known. In a study of United States veterans, the risk of PCS increased with each new SARS-CoV-2 infection(19). However, the absolute additional risk of PCS decreased sharply with each new reinfection and was not influenced by vaccination status. This could be explained by the higher proportion of infections caused by the Omicron variant among reinfections.

## Types of vaccines available and expected in 2023

As of December 2022, Québec is primarily using the Pfizer (Comirnaty®) and Moderna (Spikevax®) bivalent mRNA vaccines targeting the spike protein of the original Wuhan strain and of an Omicron subvariant. Novavax's Nuvaxovid® protein subunit vaccine, whose spike protein is derived solely from the original Wuhan strain, is available but very little used. Finally, Medicago's virus-like particle vaccine, Covifenz®, also based solely on the spike protein from the original Wuhan strain, has been approved but is unavailable. Viral vector vaccines such as AstraZeneca's Vaxzevria® or Johnson and Johnson's Jcovden® have been approved but are no longer used because of the low risk of vaccine-induced immune thrombotic thrombocytopenia (VITT).

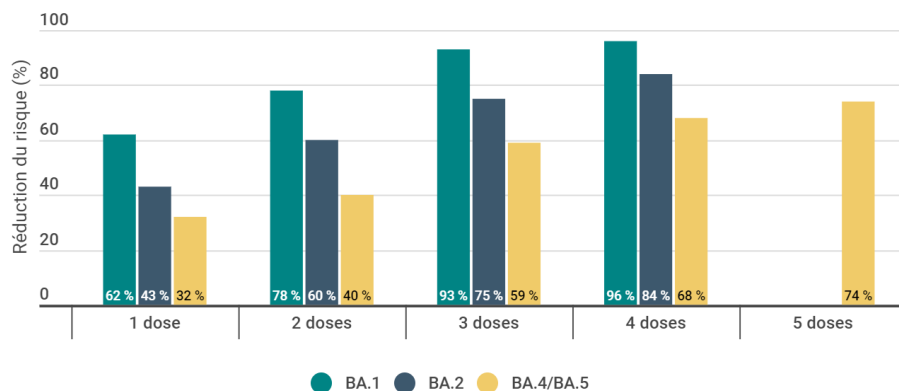
Several vaccine platforms are still being developed, but no new vaccines that can significantly improve the prevention of infections caused by the new subvariants are expected to be available in the short term.

## Vaccine effectiveness

In Québec, prior to the arrival of the Omicron variant, two doses of COVID-19 vaccine reduced the risk of hospitalization by more than 90% and the risk of symptomatic infection by 80%(1). The Omicron variant exhibits vaccine immune evasion that has increased with each of the subvariants (BA.1, BA.2, BA.4/BA.5), progressively reducing vaccine effectiveness(3,4).

In Québec, among persons aged 60 and older (excluding those residing in LTCF-CHSLDs) without prior SARS-CoV-2 infection detected by NAAT, vaccine effectiveness in preventing hospitalization due to COVID-19 has decreased with the most recent subvariants (Figure 4). For each of the subvariants, effectiveness increases with the number of doses administered when the interval since the last dose is not taken into account (Figure 4).

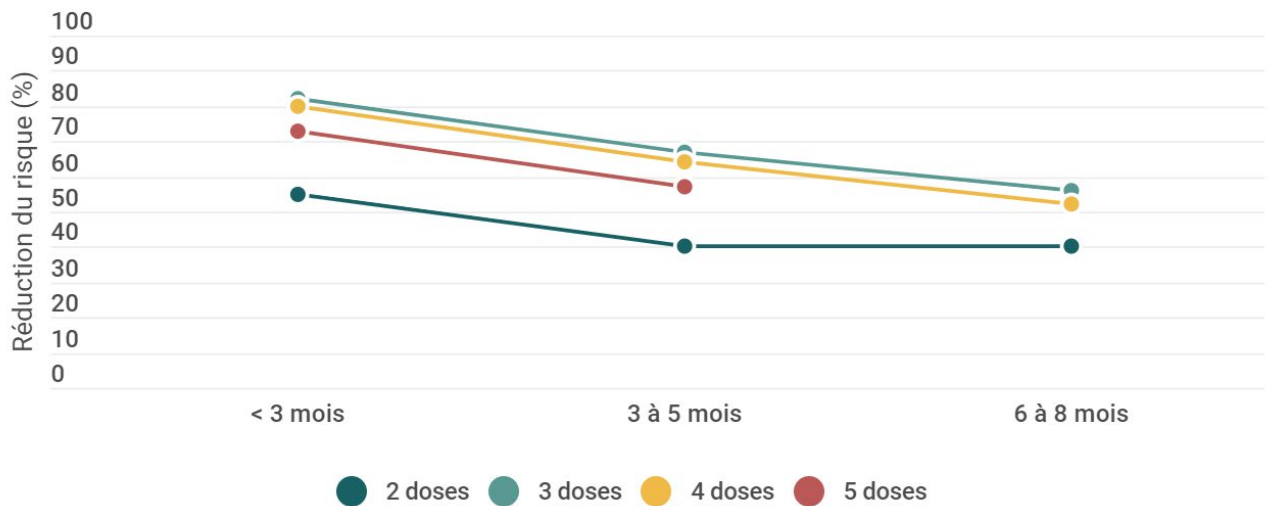
**Figure 4 Vaccine immunity: Vaccine effectiveness in preventing hospitalization due to COVID-19 in persons aged 60 and older without prior infection, by Omicron subvariant and number of doses, regardless of interval since last dose**



Source: INSPQ [Protection contre l'hospitalisation due à la COVID-19 conférée par la vaccination et l'infection antérieure chez les personnes de 60 ans et plus](#) | INSPQ

When the interval since the last dose is taken into account, it can be seen that for three or more doses, regardless of the number of doses, vaccine effectiveness is similar during the three months following the last dose and decreases similarly over time (Figure 5). As the interval since the last dose is generally shorter for persons who have received the most doses, the overall vaccine efficacy is higher among this group. In fact, each new booster dose returns protection to the level where it was immediately after the previous booster dose.

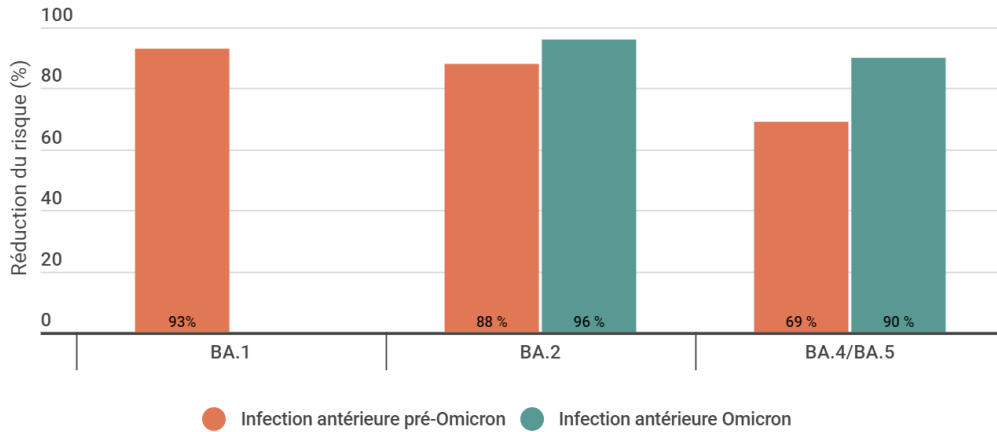
**Figure 5 Vaccine immunity: Vaccine effectiveness in preventing hospitalization due to COVID-19 in persons aged 60 and older without prior infection, by number of doses and interval since last dose, during BA.4/BA.5 subvariant predominance period**



Source: INSPQ [Protection contre l'hospitalisation due à la COVID-19 conférée par la vaccination et l'infection antérieure chez les personnes de 60 ans et plus | INSPQ](#)

An initial infection with SARS-CoV-2 induces an immune response that confers a high level of protection against hospitalization upon reinfection. This protection is somewhat higher if the prior infection was due to the Omicron variant than if it occurred before the arrival of the Omicron variant (pre-Omicron) (Figure 6).

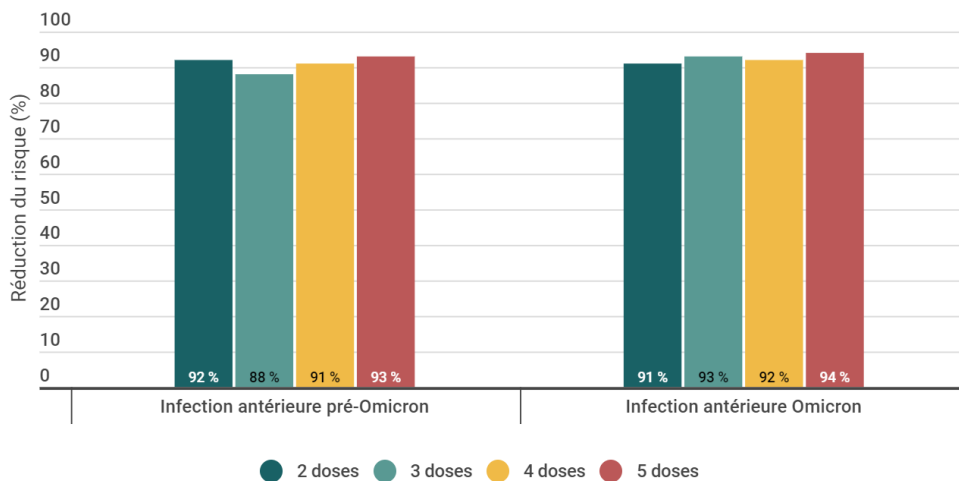
**Figure 6 Prior infection-induced immunity: Protection against hospitalization due to COVID-19 upon reinfection in unvaccinated persons aged 60 and older having had a prior infection, by subvariant**



Source: INSPQ [Protection contre l'hospitalisation due à la COVID-19 conférée par la vaccination et l'infection antérieure chez les personnes de 60 ans et plus | INSPQ](#)

Hybrid immunity, that is, immunity among individuals who have a history of prior infection and are also vaccinated, confers protection from hospitalization that is superior to vaccine immunity alone or post-infection immunity alone. This hybrid immunity appears to plateau after 2 doses of vaccine and is similar among those aged 60 and older who received 2 doses and those who received 3, 4, or 5 doses. The protection against hospitalization induced by hybrid immunity is similar regardless of whether the prior infection is old (caused by a pre-Omicron virus) or occurred more recently (caused by an Omicron subvariant). For the BA.4/5 period, protection against hospitalization upon reinfection is >90% among individuals with hybrid immunity who have received at least two doses of vaccine.

**Figure 7 Hybrid immunity: Protection against hospitalization due to COVID-19 upon reinfection with the BA.4/5 subvariant among persons aged 60 and older having had a prior infection, by number of vaccine doses**



Source: INSPQ [Protection contre l'hospitalisation due à la COVID-19 conférée par la vaccination et l'infection antérieure chez les personnes de 60 ans et plus | INSPQ](#)



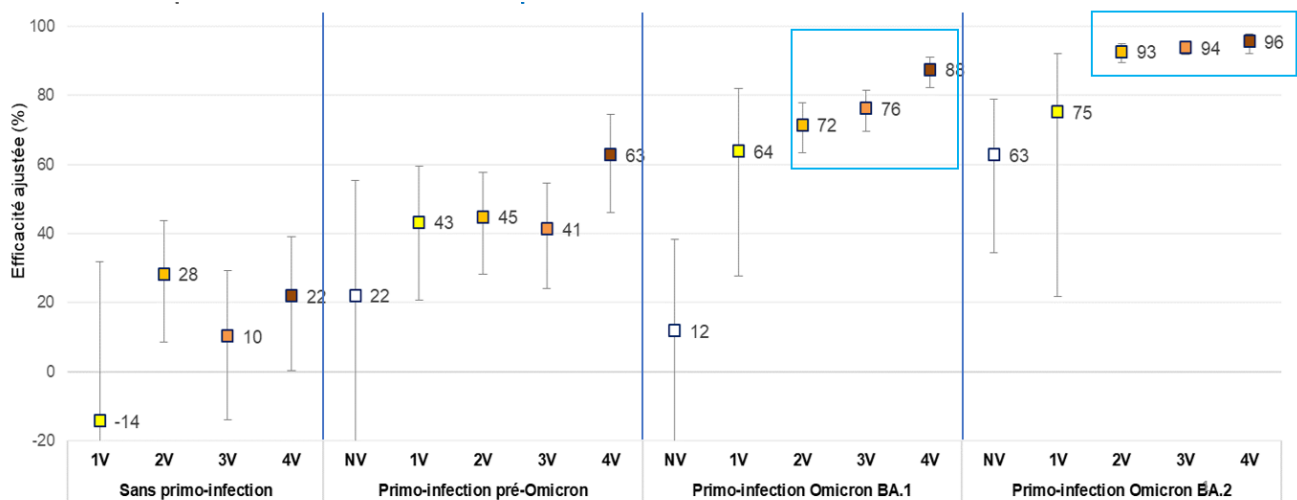
Since the arrival of the Omicron variant, many people have been using rapid antigen detection tests, the results of which were not available for this study (resulting in underestimation of the number of previous infections). The analysis of vaccine immunity therefore includes an unknown proportion of individuals who have had a prior infection, which may cause an overestimation of the vaccine effectiveness. This also affects the group of unvaccinated and uninfected individuals who serve as a control group, causing an underestimation of the protection conferred by different types of immunity.

The results of this Québec study based on the use of monovalent mRNA vaccine are aligned with those of studies published in other countries with regards to the prevention of hospitalizations due to COVID-19. These studies also show vaccine immunity decreasing over time, hybrid immunity providing greater and more durable protection with a levelling off after 3 doses of vaccine(20–25).

This Québec study only describes protection against hospitalization among persons aged 60 and older, and its findings do not apply to the risk of asymptomatic or less severe symptomatic infection, or to new subvariants (such as BQ.1.1). It leaves open the question of whether the strong protection hybrid immunity provides against hospitalization will persist more than one year.

Hospitalization among Québec health care workers (HCWs) is too rare to allow assessment of their protection against this outcome. However, their protection against symptomatic infection during the BA.4/5 predominance period reveals that vaccine immunity provides little protection regardless of the number of vaccine doses. Among the unvaccinated, immunity acquired from a prior pre-omicron infection or a BA.1 infection provides little protection, but protection is somewhat better after a BA.2 infection. It is not known whether this increased protection linked to a BA.2 infection is due to the shorter interval that has elapsed since the occurrence of BA.2 infections or to an immune response that provides better coverage against BA.4/5. Finally, hybrid immunity improves protection against symptomatic infection and increases with the number of doses and with prior infection due to a more recent subvariant (BA.2 > BA.1 > pre-omicron) (Figure 8).

**Figure 8 Protection against symptomatic COVID-19 in health care workers during the BA.4/5 predominance period, by presence of prior infection and number of vaccine doses, regardless of interval since the last dose**



## Vaccine safety

Since the beginning of the COVID-19 vaccination campaign, vaccine safety has been monitored through passive surveillance of adverse clinical events reported by health care professionals (through the adverse event component of Québec's infectious disease protection information system, the *Système d'information pour la protection en maladies infectieuses (SI-PMI), volet MCI*) and through active surveillance (CANVAS surveillance). Whereas passive surveillance reports that the frequency of adverse clinical events decreases with the number of dose, active surveillance indicates that frequencies remained similar for the first three doses(26,27). For the additional booster doses administered this fall, the same trends were observed: the bivalent vaccines did not appear to result in an increased frequency of adverse event reporting.

In the United States, active and passive surveillance data showed a higher incidence of adverse events after the 2<sup>nd</sup> dose than after the 1<sup>st</sup> or 3<sup>rd</sup> dose(28).

Although the situation may change, the safety profile of mRNA vaccines has remained stable despite the addition of booster doses, and it is likely that this will also apply to additional booster doses.

## Vaccination coverage and acceptability of booster doses

As of December 6, 2022, over 90% of the adult population had already received at least 2 doses of vaccine. The proportion having received the primary vaccination series (first 2 doses and at least one booster dose) is 54% among 18-59 year olds, 84% among 60-69 year olds, and about 90% among those aged 70 and older. Since August 15, 2022, among those who had already received their primary vaccination series, 24% of 18-59 year olds, 51% of 60-69 year olds, 63% of 70-79 year olds, and 69% of those aged 80 and older had received a new booster dose. Among chronically ill patients of all ages, 49% had received a new booster dose, but only 21% of 18-59 year olds had received one(29).

In the survey on the attitudes and behaviours of Québec adults conducted by the INSPQ from November 11 to 23, 2022, 9% of respondents said they did not intend to receive another dose at this time, because they had had COVID-19 less than three months previously(30). Even with the addition of this percentage, vaccination coverage with the fall dose remains suboptimal and may reflect some degree of vaccine fatigue. This survey reported that the main reasons given by those who do not intend to receive new doses are that they consider themselves well protected and not in need of additional doses (33%) or that there are too many doses and they do not want to receive them on a regular basis (15%). In addition, 6% said they would rather build up their immunity by catching COVID-19 than receive a new booster dose(30).

In the event that additional booster doses are recommended, vaccine coverages can be expected to be lower than those achieved with the fall 2022 booster dose.

## Feasibility

COVID-19 vaccination services are able to administer booster doses should they be recommended by the CIQ. However, to improve planning and feasibility, it would be preferable for the periodicity of these doses to remain stable.

## Conformity with other jurisdictions

Although several countries recommended fall 2022 booster doses in preparation for the 2022-23 winter season, as of December 15, 2022, these countries had not issued a recommendation for booster doses beyond that period.

In Canada, the National Advisory Committee on Immunization (NACI) strongly recommended a booster dose in the fall of 2022 for all persons aged 65 years and older and for those aged 12 and older who are at increased risk for severe COVID-19(31). NACI also recommended that all other persons between the ages of 12 and 64 be offered a booster dose in the fall:

Individuals who have received an mRNA COVID-19 vaccine as part of a fall COVID-19 vaccine booster program do not require an additional dose of a COVID-19 vaccine at this time. This includes individuals who were vaccinated using any authorized original or bivalent mRNA COVID-19 vaccine. [...] NACI continues to recommend that COVID-19 booster doses given as part of the fall program may be offered at an interval of 6 months after a previous COVID-19 vaccine dose or SARS-CoV-2 infection. However, a shorter interval of at least 3 months may be considered particularly in the context of heightened epidemiological risk, evolving SARS-COV-2 epidemiology, as well as operational considerations for the efficient deployment of the fall vaccine program. Based on what is known at this time about the virus and vaccines, it is not expected that a booster dose will be routinely provided every 3 months.

In the United States, the Advisory Committee on Immunization Practices (ACIP) has recommended that persons aged 5 and older who have already received their primary vaccination series (2 doses for immunocompetent persons and 3 doses for immunocompromised persons) receive a dose of bivalent vaccine after a minimum interval of 2 months since the last dose of monovalent vaccine(32).

In France, the Haute Autorité de santé (HAS) has recommended that a booster dose be given, regardless of the number of booster doses previously given, to persons at risk of severe disease including:

People aged 60 and older, immunocompromised patients regardless of age, adults under 60 identified as being at risk of severe disease, pregnant women from the first trimester onwards, children and adolescents at high risk suffering from pathologies that justify it, persons sharing a living environment or in regular contact with immunocompromised or vulnerable persons, including professionals in the health and medico-social sectors(33). This additional booster dose must respect the minimum recommended interval between two booster doses, namely: i) three months for persons aged 80 and older, for residents in LTCF (EHPADs or USLDs), for immunocompromised persons; ii) six months for others. For those who have been infected with SARS-CoV-2, an additional booster dose is still recommended a minimum of three months after infection. [Translation]

In the United Kingdom, the Joint Committee on Vaccination and Immunization (JCVI) recommended a booster dose for the fall of 2022 for persons at high risk of severe COVID-19; namely, residents in seniors' care homes and staff working in seniors' care homes, frontline health and social care workers, all adults aged 50 years and older, persons aged 5-49 years with diseases that increase risk, persons aged 5 to 49 years who are household contacts of people with immunosuppression, and persons aged 16-49 years who are caregivers(34).

## CIQ recommendations

Given the strong protection against hospitalization afforded to persons with hybrid immunity following from an initial episode of COVID-19 and administration of at least 2 doses of mRNA vaccine, and given that this protection is weaker and less durable for vaccinated persons who have never been infected, vaccine recommendations should be stratified according to prior infection status.

Since January 2022, the proportion of the population that has been infected has increased substantially. Because of the limited ability of available vaccines to prevent infection due to the Omicron variant and its subvariants, it seems clear that virtually the entire population will be infected, in the short or long term. Despite this, vaccines remain an essential tool given their effectiveness in preventing severe cases of COVID-19, primarily those leading to hospitalization or death. Although long COVID or PCS is a severe form of COVID-19 that can affect all population groups, there exists no scientific evidence that additional booster doses would reduce the frequency or severity of PCS among persons who have already received the primary vaccination series (2 doses + one booster) but this remains plausible.

The greatest gain in terms of preventing hospitalizations and deaths will be achieved by ensuring vaccination of those at high risk of complications who have not yet been infected. At the field level, a person who reports having had COVID-19 confirmed by a NAAT or by a rapid antigen test will be considered to have been previously infected with SARS-CoV-2.

**The CIQ recently recommended a booster dose of bivalent vaccine for high-risk individuals who had not yet had the disease and had never received a bivalent vaccine, to be given 6 months after the last dose received(35). The CIQ is extending this recommendation to all high-risk individuals who have not yet been infected and whose last dose was administered at least 6 months ago, regardless of the product previously used. These high-risk individuals were defined in a previous statement regarding COVID-19 vaccination <https://www.inspq.qc.ca/publications/3219-vaccination-influenza-covid-2022>. This dose is also recommended for all immunocompromised persons aged 5 and older, whether or not they have been infected. Administration of a dose less than six months after the previous dose is not recommended but should not be considered an administrative error if it occurs.**

The COVID-19 situation is constantly evolving and the CIQ will continue to adjust its vaccine recommendations based on the epidemiology of the disease and the most recent scientific knowledge.

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## Administration of COVID-19 booster doses: Recommendations for winter and spring 2023

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