

Preliminary Data on Vaccine Effectiveness and Supplementary Opinion on the Strategy for Vaccination Against COVID-19 in Quebec in a Context of Shortage

COMITÉ SUR L'IMMUNISATION DU QUÉBEC

February 12, 2021

Context

On December 18, 2020, and January 15, 2021, the Comité sur l'immunisation du Québec (CIQ) issued a recommendation in a context of COVID-19 vaccine shortage: to offer an initial dose of the vaccine to the greatest number of individuals belonging to the first six priority groups (1,2). This recommendation was based on efficacy of over 90% observed in Phase 3 clinical trials from 14 days after the initial dose for both the BNT162b2 vaccine (Pfizer-BioNTech) and the m-RNA 1273 vaccine (Moderna), and on the findings with other (non-COVID-19) vaccines that post-vaccine immunity is generally maintained for a long period and that the response is better with a longer interval between doses.

In these opinions, the CIQ also highlighted the importance of closely monitoring the vaccines' effectiveness against COVID-19 in normal conditions of use (public health programs) so that any necessary adjustments to the vaccination strategy may be made quickly.

The Ministère de la Santé et des Services sociaux (MSSS) recently asked the CIQ to issue an opinion on the target interval before administration of the second dose, and important considerations to be taken into account for decision-making. The purpose of this opinion is to answer this question through an analysis of the most recent data on COVID-19 vaccine effectiveness from Quebec and abroad.

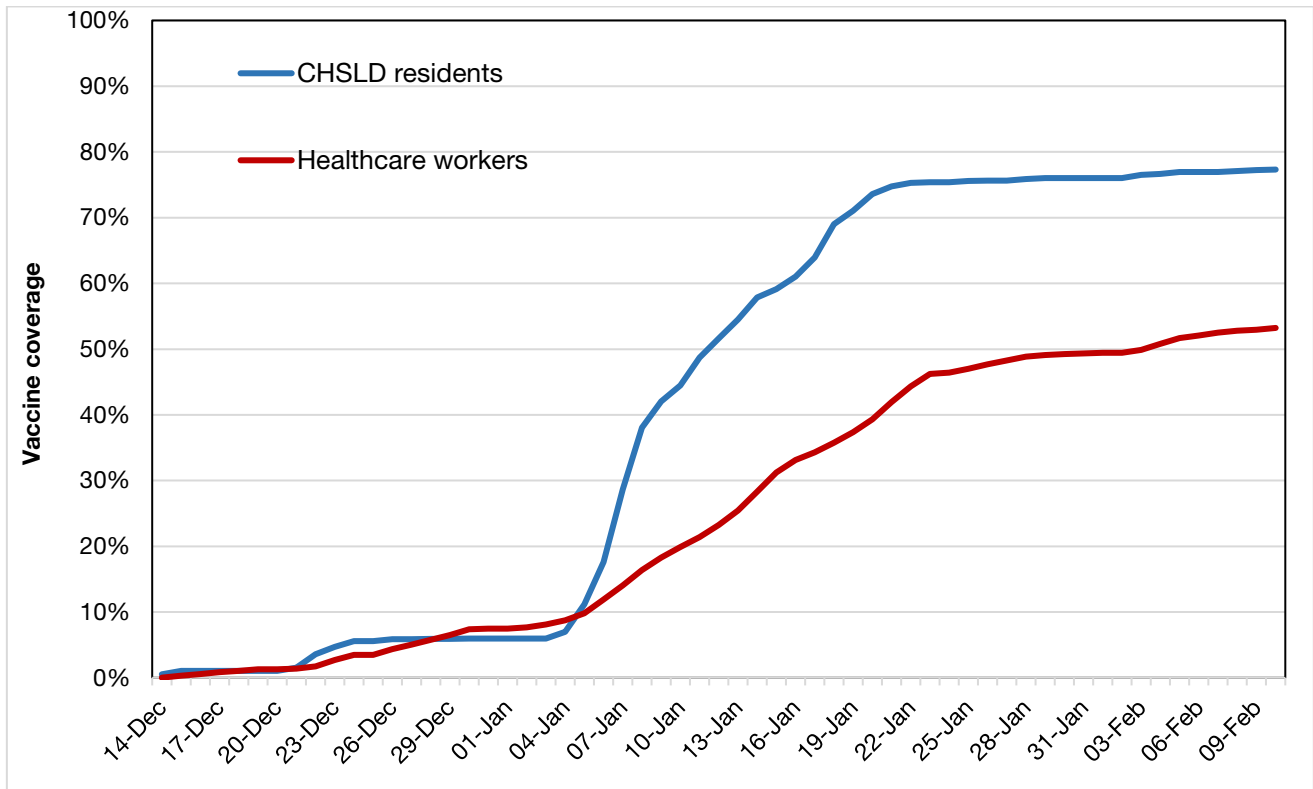
Analyses of Quebec data, February 10, 2021

Vaccine coverage

As at February 10, 2021, according to the Québec Vaccination Registry's data, 33,331 (78%) of 43,110 residents at CHSLDs (centres d'hébergement de soins de longue durée [residential and long-term care centres]) (denominator estimated by the number of licensed beds) and 172,979 (53%) of 325,000 healthcare workers (HCWs) in the public network had received an initial dose of the COVID-19 vaccine (Figure 1). Some individuals who are working in healthcare establishments but are not employees of the public network (e.g., employees of private agencies) may have been vaccinated, which would lead to an overestimation of the vaccine coverage presented here.

Nearly 75% of doses administered were the Pfizer-BioNTech vaccine, and 25% were the Moderna vaccine. It should be noted that both vaccines have very similar characteristics and response profiles in terms of safety, immunogenicity, and efficacy (3,4).

Figure 1 Vaccine coverage with one dose of the COVID-19 vaccine among CHSLD residents and healthcare workers in Quebec, December 14, 2020, to February 10, 2021

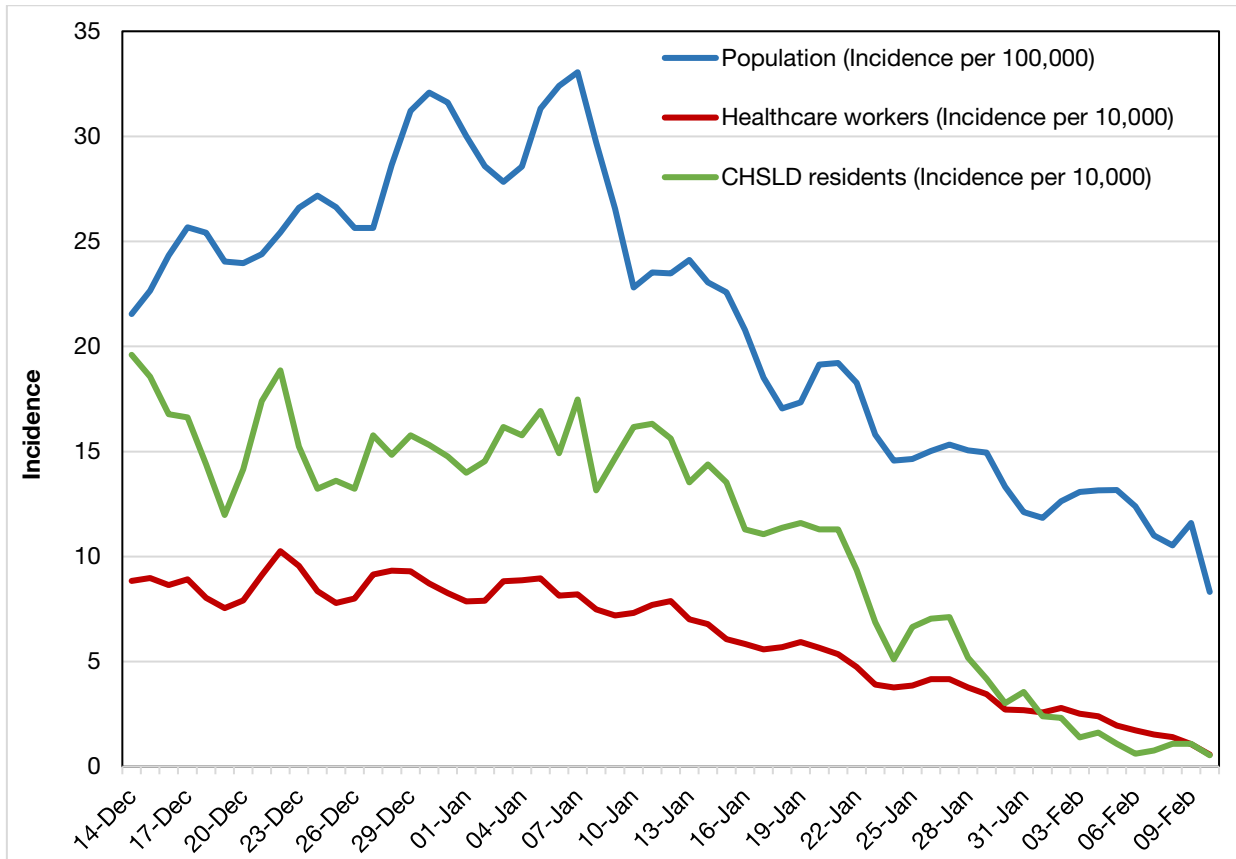


Source: Vaccination Registry .

Incidence of COVID-19 in the population, among healthcare workers and among CHSLD residents

From the start of January to February 10, 2021, the incidence of COVID-19 in Quebec decreased significantly among both the general population and HCWs and CHSLD residents (Figure 2).

Figure 2 Daily smoothed incidence of COVID-19 in the general population, among healthcare workers and among CHSLD residents in Quebec (December 14, 2020, to February 10, 2021)



Source: TSP information system.

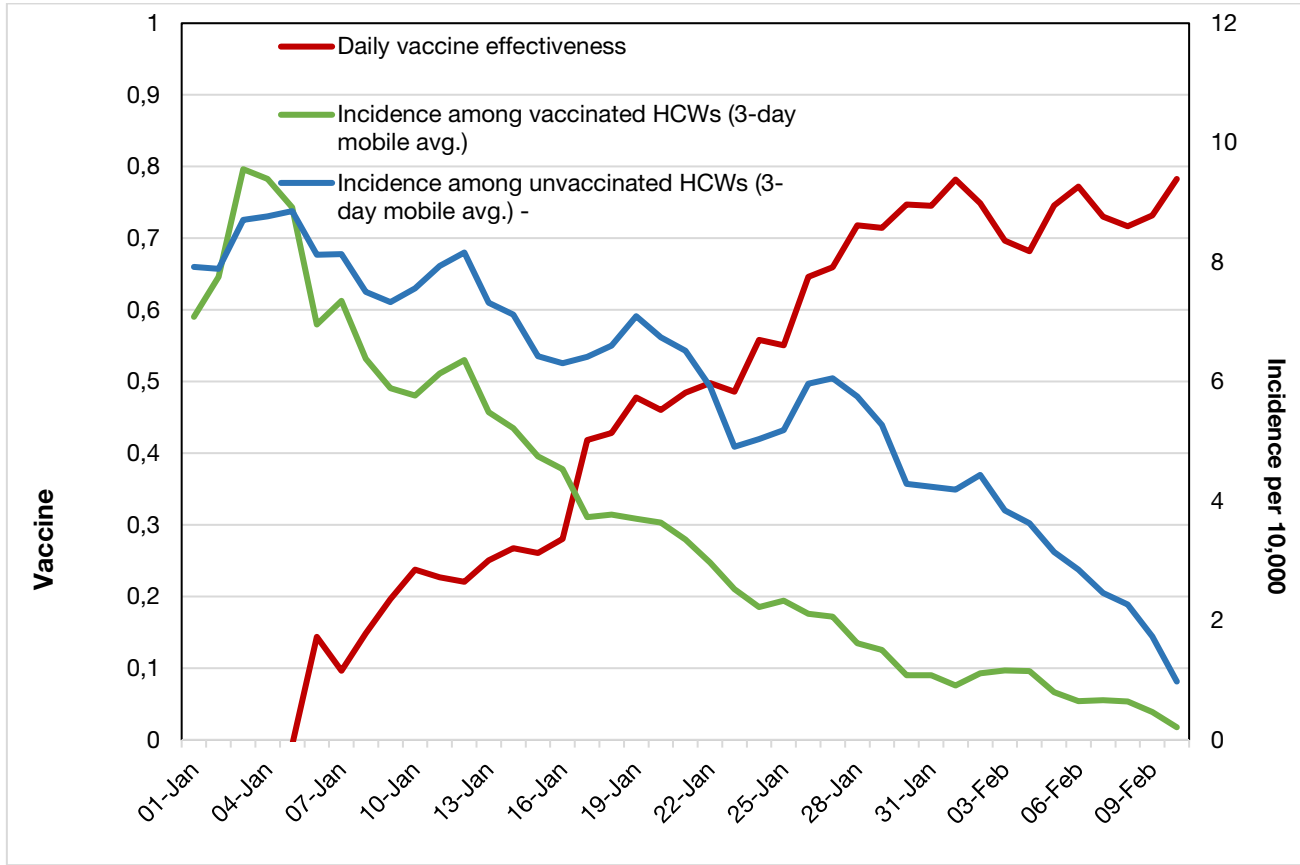
Effectiveness of COVID-19 vaccines among healthcare workers

Vaccine effectiveness was estimated using two methods: comparing the incidence rates among vaccinated and unvaccinated HCWs, and comparing the incidence among vaccinated HCWs only, at various intervals following vaccination.

Comparison of incidence rates among vaccinated and unvaccinated HCWs

In Figure 3, the daily COVID-19 incidence rate (person-days of observation in the denominator) among HCWs, smoothed over 3 days, is compared between unvaccinated (blue curve) and vaccinated HCWs (green curve). Vaccinated workers are included in the calculation of rates of unvaccinated individuals until the day they are vaccinated. The red curve indicates vaccine effectiveness (1 minus the ratio of incidence rates among vaccinated and unvaccinated individuals). This curve does not take into account the delay between the vaccination and the development of vaccine protection. Between January 1 and February 10, 2021, there is a gradual increase in vaccine effectiveness resulting from the growing proportion of vaccinated individuals reaching the period where they have developed vaccine immunity.

Figure 3 Incidence of COVID-19 among vaccinated and unvaccinated healthcare workers in Quebec and vaccine effectiveness from January 1 to February 10, 2021



Data source: Combined from TSP information system and the Vaccination Registry

Effectiveness reaches nearly 80 % at the end of the period (Figure 3). This indicator underestimates the real effectiveness of the vaccine because the HCWs who had access to vaccination were those with greater exposure to infected patients than those who were not offered vaccination, because it does not take into account the elapsed time after vaccination, and because symptom onset date was unavailable for 28 % of sick workers. As this later information was unavailable, the date that had to be used was the date that illness was detected, which generally follows the onset of illness by a few days.

Comparison of incidence rates among vaccinated and unvaccinated HCWs at various intervals following vaccination

As it takes around 14 days to develop vaccine immunity, the incidence of illness in the first 9 days following vaccination is similar to that of an unvaccinated group. Comparing the incidence of COVID-19 during this period at various intervals following vaccination, there is an over 70 % reduction in incidence starting 14 days or more after vaccination (Table 1). With this approach, the decreasing incidence in the population for this period may cause an overestimation of vaccine effectiveness (VE), while two of the biases mentioned above (related to the higher risk among the first HCWs vaccinated and the actual date of symptom onset versus the available reference date) would tend toward an underestimated VE. It is reassuring that both approaches show converging results.

Table 1 Incidence of COVID-19 among vaccinated healthcare workers by interval following vaccination, and estimated vaccine effectiveness based on incidence in the <10-day-period versus other intervals

	Interval following vaccination				
	<10 days	10-13 days	14-20 days	21-27 days	≥28 days
Cases	901	211	149	90	94
Person-days	1,560,866	590,450	983,099	751,451	798,475
Incidence per 10,000 person-days	5.77	3.57	1.52	1.20	1.18
Vaccine effectiveness (%)	Reference	38.1 %	73.7 %	79.3 %	79.6 %

Effectiveness of COVID-19 vaccines among CHSLD residents

As CHSLD residents were not included in the Phase 3 clinical trials, it is especially important to closely monitor the effectiveness of mRNA COVID-19 vaccines among this population, which is older and more vulnerable than the clinical trial participants. This type of evaluation was initially performed for the first two CHSLDs to receive the vaccination (Appendix 2), and followed by a preliminary evaluation of all CHSLDs in Quebec (below).

As there were very few CHSLD residents who were not vaccinated, and this group mainly consisted of individuals who had recently had COVID-19 or were at the end of their lives, it is not appropriate to estimate the VE by comparing the incidence of COVID-19 among vaccinated versus unvaccinated residents. The VE was estimated by comparing the incidence of illness over the first 9 days following vaccination to the incidence observed at different intervals following vaccination. We see a decrease in incidence of around 50% between 14 and 20 days after vaccination, and of around 80% between 21 and 27 days after vaccination (Table 2). A trend toward a higher VE 28 days or more after vaccination is also observed, but this trend remains to be validated with a larger group of monitored individuals. Immunosenescence could explain the longer time required to observe vaccine protection (5). Here as well, the much lower incidence within the general population at the end of the period compared with that at the start of January creates a bias leading to overestimation of the VE, while the actual date of symptom onset in relation to the available reference date would tend toward an underestimated VE.

Table 2 Incidence of COVID-19 among vaccinated CHSLD residents by interval following vaccination, and vaccine effectiveness

	Interval following vaccination			
	<10 days	10-13 days	14-20 days	21-27 days
Cases	506	167	173	59
Person-days	247,613	96,548	166,770	146,364
Incidence per 10,000 person-days	20.44	17.30	10.37	4.03
Vaccine effectiveness (%)	Reference	15.4 %	49.2 %	80.3 %

It is important to note that these are preliminary VE estimates. Work is currently underway to refine the analyses and make adjustments to take certain possible biases into account. These results must therefore be interpreted with caution.

Israeli data on the effectiveness of COVID-19 vaccines

Israel is the country with the largest proportion of the population vaccinated with an mRNA vaccine, which facilitates rapid collection of data on vaccination effectiveness. As two doses are available at a 21-day interval, it will, however be difficult to evaluate the effectiveness of a single dose in this context, except for the short period preceding administration of the second dose. A first non-peer-reviewed study of the effectiveness of the Pfizer-BioNTech vaccine against symptomatic and asymptomatic infection has been made available (6). It concludes that the vaccine achieved 51% effectiveness 13 to 24 days following the initial dose. The most significant limitation of this study is the fact that the authors included a number of days in the monitoring period where vaccine protection had not yet had sufficient time to develop. As the reference date used was the sampling date, which is often after the date of symptom onset, it seems too early to begin monitoring at 13 days, which may result in an underestimated VE. A reanalysis of the data by Hunter and Brainard (7) showed a VE that gradually increased from 13 to 23 days following vaccination, reaching nearly 90% after 21 to 23 days. The authors also noted an increase in the incidence of infection 8 days after vaccination, which could suggest that vaccinated individuals engaged in riskier behaviours after the initial injections before vaccine protection could be established (8).

Data published on the prevention of more severe illness (hospitalization and death) are not yet available but we can expect the VE to be similar or higher (3.9) for these outcomes.

Vaccine immunogenicity

In the clinical studies on the Pfizer-BioNTech vaccine, lower concentrations of antibodies were found in elderly individuals following vaccination (10). Other studies have demonstrated lower immunogenicity from a single dose of the Pfizer-BioNTech vaccine among individuals aged 80 and above (11). It is important to note that there is no immunological correlate of protection in humans and that experimental studies have demonstrated protection through low levels of neutralizing antibodies in the serum (12). At present, the preliminary data on VE in Quebec do not demonstrate significantly lower protection among older individuals compared to younger individuals.

Selective pressure after vaccination

Concerns have been raised on the theoretical possibility that a longer interval between vaccine doses could promote the emergence of SARS-CoV-2 variants by allowing the virus to multiply in the presence of low levels of antibodies. However, the theoretical risk of exerting pressure on SARS-CoV-2 with a single dose of the vaccine must be weighed against the real and serious consequences of high transmission of the virus among vulnerable populations. That said, variants primarily emerge when the virus infects a large number of susceptible individuals who also have weakened immune systems (e.g., immunosuppressed individuals). The greatest possible number of vulnerable individuals should be protected in the short term in a context of vaccine shortage; an extended interval between doses allows for the vaccination of a larger number of individuals. Finally, scientific knowledge on vaccines does not suggest that such an extension would have a negative impact on immune response after the second dose; it suggests the opposite. Some of these points align with the position adopted by the British Society for Immunology, who issued a favourable opinion on extending the interval between vaccine doses in the United Kingdom to 12 weeks (13).

More broadly speaking, there are a number of unknowns regarding the effectiveness of mRNA vaccines against the various SARS-CoV-2 variants currently emerging. The data on effectiveness against these variants should be closely monitored both in Quebec and around the world. If lower effectiveness against certain variants in Quebec is observed, the vaccine strategy may need to be adapted.

Modelling data

A growing body of modelling work suggests that vaccinating a larger number of priority groups with a single dose in the context of vaccine shortage prevents more hospitalizations and deaths than a strategy of administering two doses to fewer groups according to the schedule recommended by the manufacturer, even with a lower VE after one dose (14).

Summary

The data available on the efficacy of mRNA vaccines against COVID-19 in Phase 3 studies (clinical studies) and their effectiveness in studies monitoring the rollout (public health programs) remain limited at present time. It is, however, possible to identify certain preliminary trends:

- ▶ The VE of a single dose of mRNA vaccines against COVID-19 appears high in the short term. It is likely that field effectiveness would be lower than the efficacy demonstrated in Phase 3 studies (92 %), one reason being that clinical trial participants are younger and in better health than the general population.
- ▶ The VE appears high among both older people (e.g., aged 80 and above) and younger people (e.g., healthcare workers). From the data currently available, it is not possible to determine if effectiveness is significantly lower among particularly frail seniors, especially those residing in CHSLDs.
- ▶ The VE for preventing illness seems to appear in 14 days among younger people and 21 days among older people. Maximum effectiveness might not be reached within 21 days among younger people or within 28 days among older people. It is plausible that the effectiveness for preventing serious infections, including those leading to hospitalization or death, begins sooner, but the data are not yet available for these outcomes.
- ▶ It is too early to determine at what point there would be a decrease in the effectiveness of a single dose as the maximum monitoring period of vaccinated individuals is less than two months. The studies are still underway and the data are analyzed on a weekly basis.

- From the data available on mRNA vaccines, it is not currently possible to determine the degree of additional protection from the second dose and the ideal interval between both doses of the vaccines to maximize long-term protection.

Recommendations

In view of the information presented here, the Comité sur l'immunisation du Québec recommends maintaining the proposed strategy for a context in which there is a COVID-19 vaccine shortage and high circulation of the virus, which is to provide an initial dose of the vaccine to the greatest possible number of individuals belonging to the first six priority groups. The CIQ reiterates that the second dose is important and must be made available, but it is currently difficult to determine the optimal time at which it should be administered. The CIQ also reiterates the importance of monitoring, in near-real time, the effectiveness of COVID-19 vaccines in Quebec for different age groups, and closely monitoring international data on this issue, which will help determine the right time for the second dose of the vaccine. A shorter interval before the second dose could be recommended if effectiveness is observed to be significantly lower than anticipated or if a decline in protection over time is observed. As there is no such evidence at present, a longer interval should be prioritized over a shorter one in a context of vaccine shortage to maximize the protection of the most possible people.

The CIQ recommends to clearly inform vaccinated individuals about the 14–28 day interval, depending on their age group, necessary to reach optimal protection against the illness. Considering this interval and the fact that VE remains imperfect, it is essential for vaccinated individuals to avoid behaviours that increase their risk of infection after they are vaccinated.

The CIQ recommends continuing efforts (e.g., access to vaccination, good communication, information capsules) to increase the proportion of healthcare workers who receive an initial dose of the vaccine. Higher vaccine coverage allows healthcare workers to reduce their risk of developing the illness, protect the integrity of the healthcare system, and potentially reduce the risk of introducing SARS-CoV-2 to environments like CHSLDs, private seniors' residences, and hospital centres, or spreading it in these settings.

Appendix 1 Update to the contribution of priority groups to the burden caused by COVID-19

The CIQ has proposed a preliminary priority order of the groups to be vaccinated (15). The contribution to the number of cases, hospitalizations, admissions to intensive care units (ICUs), and deaths between September 1, 2020, and January 16, 2021, varies widely between the first priority groups (Table 3).

Table 3 Priority order for vaccination against COVID-19 in Quebec and percentages of all cases, hospitalizations, admissions to the ICU, and deaths between September 1, 2020, and January 16, 2021, by group

Rank	Group	Estimated number	Cumulative number	Cases % (n)	Hospitalizations % (n)	ICU % (n)	Deaths % (n)
1	CHSLD residents	40,000	40,000	2.9% (5,304)	4.4% (450)	2.3% (37)	37.9% (1,481)
2	Healthcare Workers	325,000	365,000	12.1% (21,878)	2.7% (272)	2.6% (42)	0.1% (4)
3	Individuals living in private seniors' residences	136,000	501,000	4.3% (7,699)	23.0% (2,327)	8.6% (140)	26.9% (1,050)
4	Residents of isolated and remote communities	46,000	547,000	N/A	N/A	N/A	N/A
5	Individuals aged ≥ 80 years in the community*	418,000	965,000	2.7% (4,898)	18.9% (1,919)	12.5% (203)	19.8% (773)
6	Individuals aged 70-79 years in the community*	768,000	1,733,000	3.7% (6,776)	17.2% (1,742)	26.5% (430)	10.0% (391)
	Subtotal of groups 1 to 6	1,733,000		25.7%	66.2%	55.5%	94.7%
7	Individuals aged 60-69 years in the community*	1,148,000	2,881,000	7.0% (12,582)	13.7% (1,384)	22.3% (362)	3.7% (146)
	Total of groups 1 to 7	2,881,000		32.7%	79.9%	74.8%	98.4%

Source: Extracted from the database Trajectoire de santé publique (TSP), MSSS), February 5, 2021. N/A = not available.

* The estimated and cumulative numbers include individuals in CHSLDs and private seniors' residences and HCWs, but cases, hospitalizations, admissions to intensive care units, and deaths in individuals living in the community exclude residents of CHSLDs and private seniors' residences and HCWs.

CHSLD residents have the highest proportion of deaths (37.9%); individuals 70 to 79 years old living in the community have the highest rate of ICU admissions (26.5%); and the percentage of all hospitalizations is high for individuals living in private seniors' residences (23.0%), individuals ≥80 years old (18.9%), and individuals 70 to 79 years old (17.2%) living in the community. Healthcare workers make up 12.1% of all COVID-19 cases in Quebec while only representing 3-4% of the total population. Together, individuals living in CHSLDs and private seniors' residences, healthcare workers, and individuals ≥70 years old in the community represent 25.7% of cases, 66.2% of hospitalizations, 52.5% of ICU admissions, and 94.7% of deaths in Quebec. The rapid vaccination of these groups would help substantially reduce the burden of COVID-19, especially severe cases (hospitalizations and deaths).

Appendix 2: Transmission of COVID-19 in the first two CHSLDs to receive the vaccination

The incidence of COVID-19 in the first two CHSLDs targeted for vaccination against this illness was evaluated by the regional public health unit, in collaboration with the CIQ. This evaluation was made on January 19, 2021, and data on the prevention of serious illness and death in one of the two CHSLDs were added on February 2, 2021.

In the first CHSLD, 88% of residents (195/221) and 56% of healthcare workers were vaccinated on December 14 and 15, 2020, with the Pfizer-BioNTech product. A COVID-19 outbreak was detected 5-6 days before the start of vaccination, and most patients eventually fell ill as a result. A number of cases occurred among vaccinated patients 14 days or more after they received the first dose of the vaccine. By January 19, 2021, of the 146 cases among vaccinated patients, 44% (64) appeared less than 14 days after they received their dose of the vaccine, 49% (71) appeared between days 14 and 20, and 8% (11) appeared 21 days or more after vaccination. No cases were observed among vaccinated individuals more than 25 days after vaccination, but there were also no further cases among those who were not vaccinated. Epidemiological analyses did not reveal vaccine protection among the residents, but did determine significant effectiveness among healthcare workers starting 14 days after the first dose. However, an analysis on February 2, 2021, estimated that the vaccine effectiveness among residents after 14 days was around 40% for preventing serious infections, and around 50% for preventing death. The analysis of the situation and epidemic curves reveals successive transmission at the different wards and rules out a single source of transmission, such as, for example, a contagious vaccinator.

In the second CHSLD, 82% of patients (260/315) and 39% of healthcare workers (255/650) were vaccinated in mid-December with the Pfizer-BioNTech product. A COVID-19 outbreak began on October 28, 2020, and an epidemiological investigation was launched on November 26. The vast majority of cases had occurred before the start of vaccination. By December 14, 2020, the outbreak had already affected 179 individuals (89 residents, 80 employees, 9 caregivers/visitors, and 2 “others”). The number of cases began to decline after December 5, six days before vaccination began. On January 19, 2021, 8 cases were identified, consisting of 7 residents and 1 healthcare worker, 14 or more days after vaccination. The majority of cases among residents occurred between 21 and 27 days after vaccination. Because of the small number of cases, it was not possible to estimate vaccine effectiveness.

After the phylogenetic analysis, the size of these outbreaks did not appear to be explained by the presence of a strain that was particularly transmissible or could have bypassed the vaccine immunity.

The analysis of these two outbreaks raised concerns about the vaccine protection in CHSLD patients. At the time, the main hypotheses were: 1) that the protection conferred by an initial dose among very old individuals suffering from multiple chronic illnesses is suboptimal, particularly in the prevention of milder illness, or 2) that this protection requires more than 14 and even 21 days to develop, possibly due to immunosenescence.

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The French version is entitled *Données préliminaires sur l'efficacité vaccinale et avis complémentaire sur la stratégie de vaccination contre la COVID-19 au Québec en contexte de pénurie* is also available on the website of the Institut national de santé publique du Québec at: www.inspq.qc.ca/publications/3111-donnees-preliminaires-efficacite-vaccinale-strategie-covid19

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