Superior
Health Council

BOOSTER VACCINATION AGAINST COVID-19 FOR THE GENERAL POPULATION

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SHC № 9683

.be

Federal Public Service Health, Food Chain Safety and Environment

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Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL no. 9683

Booster vaccination against COVID-19 for the general population

In this scientific advisory report, which offers guidance to public health policy-makers, the Superior Health Council of Belgium provides recommendations of the need of a booster vaccination against COVID-19.

This version was validated by the Board on December 1 2021[1]

I INTRODUCTION

The Superior Health Council (SHC) received a request for advice from the Interministerial Conference (IMC) on November 10 2021 on the need of a booster dose for Coronavirus disease 2019 (COVID-19) vaccination.

A difference must be made between booster doses and additional doses. The World Health Organization (WHO) defined both as in the interim statement published on October 4 2021:

- **Booster doses** are administered to a vaccinated population that has completed a primary vaccination series (currently one or two doses of COVID-19 vaccine depending on the product) when, with time, the immunity and clinical protection has fallen below a rate deemed sufficient in that population. The objective of a booster dose is to restore vaccine effectiveness from that deemed no longer sufficient.

- **Additional doses** of a vaccine may be needed as part of an extended primary series for target populations where the immune response rate following the standard primary series is deemed insufficient. The objective of an additional dose in the primary series is to optimize or enhance the immune response to establish a sufficient level of effectiveness against disease. In particular, immunocompromised individuals often fail to mount a protective immune response after a standard primary series, but also older adults may respond poorly to a standard primary series.

In Belgium, **an additional dose** is already implemented for immunocompromised patients (KCE, 2021). **Booster doses** are implemented for individuals who received one dose of the COVID-19 Vaccine Janssen® (SHC 9677, 2021), elderly (> 65 years), individuals living in care facilities such as nursing homes (SHC 9650, 2021) and healthcare workers (SHC 9679, 2021).

The IMC notes that the current epidemiological situation is worrying. The number of people who fall ill, are hospitalized or die has risen sharply since October 2021. The pressure on the healthcare system is particularly high. This applies to the hospital system, which today devotes about a quarter of its intensive care capacity to COVID-19 care. This part will increase and again lead to the postponement of other care, not related to COVID-19. Front line workers are

[1] The Council reserves the right to make minor typographical amendments to this document at any time. On the other hand, amendments that alter its content are automatically included in an erratum. In this case, a new version of the advisory report is issued.

also under heavy workload, as they have to provide regular care as well as testing and advising people with symptoms and high risk contacts. Prospective models show that the peak in hospital load of this fourth wave will not be reached before – at least – mid December. The height of the fourth wave and its duration are currently uncertain, as this depends on the evolution of voluntary and imposed behavioural changes of the entire population.

In this context (and for prevention of potential future waves), it is therefore imperative to reduce the circulation of the virus and not only focus on reduction of severe disease, Intensive Care Unit (ICU) admission or death. Reduced circulation of the virus will better protect the general population against illness, hospitalization and death but also protect those fully vaccinated with a weaker immune system (lower or no response on vaccination).

However, in periods of high virus circulation (peak of wave), there are no perfect or unique instruments to prevent infection and transmission. What is needed is a combination of actions such as ventilation measures, hand hygiene, masks, physical distance, indoor contact reduction, quarantine, isolation **and** vaccination. These actions require an effort from each of us.

II RECOMMENDATION

1) Primary vaccination remains priority in the fight against severe forms of COVID-19 and must be continued to be strongly promoted.

2) The SHC reiterates the importance of the rapid implementation of a booster dose for the groups previously determined.

Based on current (inter)national data and trends which are evolving quickly over time:

- At this moment, the effectiveness of the COVID-19 vaccines available in Belgium against severe forms of the disease remains proven for the general population under 65 years of age.

- Based on international preprint studies and data from Sciensano, protection against (a)symptomatic infection seems to wane more rapidly over time compared to protection against serious disease or mortality in fully vaccinated people. At this moment, data are scarce on the effect of a booster dose of COVID-19 vaccination on vaccine-induced immunity and duration of protection against severe outcome and (symptomatic) infection of COVID-19.

- The reduction of (a)symptomatic COVID-19 infection reduces the risk of transmission.

- The relative reduction in hospital admissions in people over 65 years of age who received a booster dose seems already noticeable (preliminary data from international studies).

- The booster dose has been authorized by the European Medicines Agency (EMA) for mRNA vaccines Comirnaty® (full dose) and Spikevax® (1/2 dose) for people over 18 years of age.

3) **Based on these data, the SHC recommends a booster dose with an mRNA vaccine (full dose for Comirnaty® - ½ dose for Spikevax®[2]) for all persons over 18 years of age to prevent hospitalizations, infections and transmission.**

➔ In addition, this booster dose with an mRNA vaccine should be administered **in the same order of priority as the primary vaccination** and at least 2 to 6 months after the end of the primary vaccination (table below).

Primary vaccination	**Type of primary vaccine**	**Primary vaccination schedule**	**Booster vaccination schedule**
Spikevax® (Moderna)	mRNA	2 doses Spikevax®	>6 months booster of mRNA vaccine
Comirnaty® (BioNTech/Pfizer)	mRNA	2 doses Comirnaty®	>6 months booster of mRNA vaccine
Vaxzevria® (AstraZeneca)	Viral Vector	2 doses Vaxzevria®	>4 months booster of mRNA vaccine
COVID-19 Vaccine Janssen®	Viral Vector	1 dose COVID-19 Vaccine Janssen®	>2 months booster of mRNA vaccine

➔ In addition, **the SHC recommends the administration of the Comirnaty® vaccine <u>as primovaccination</u> for persons under 30 years of age** (based on preliminary findings of Nordic countries (GACVS, 2021) and a French study (EPI-PHARE, 2021) showing an increased risk of myocarditis and pericarditis after the Spikevax® vaccine - observed in young men under 30 years old after primary vaccination - in comparison with the Comirnaty® vaccine).

➔ **As a precaution, the SHC prefers the administration of the Comirnaty® vaccine <u>as a booster dose</u> for persons under 30 years of age**. However, at present, we do not have any evidence of the effect of the ½-dose booster Spikevax® on the incidence of myocarditis and pericarditis (dose-related effect?). Therefore, it is possible for TF Vaccination to temporarily not take into account this precautionary recommendation, waiting for more data.

The relationship between levels of antibody titers and the necessity of a booster dose is not yet clear (SCH 9634, 2021). Furthermore, for practical reasons, it is unfeasible to study antibody titers to decide on the necessity of a booster at an individual level. An infection after completion of primary vaccination will certainly have a booster effect. However, first data show large individual variation so we can't conclude yet on the duration and impact of a COVID-19 infection as a booster effect.

➔ Therefore, **the SHC recommends a booster vaccination be given regardless of history of COVID-19 infection, and at least 14 days after** recovery of symptomatic COVID-19, or at least 14 days after a positive Polymerase Chain Reaction (PCR) test for asymptomatic COVID-19.

[2] whatever the age or the primary schedule received

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III METHODOLOGY

The request was treated by the standing group Vaccination (NITAG) including experts in microbiology, infectiology, epidemiology, vaccinology and general medicine. The experts of this working group provided a general and an *ad hoc* declaration of interests and the Committee on Deontology assessed the potential risk of conflicts of interest.

This advisory report is based on a review of the scientific literature published in both scientific peer-reviewed journals, preprint articles and reports from national and international organisations competent in this field, as well as on the opinion of the experts.

Once the advisory report was endorsed by the NITAG, it was ultimately validated by the members of the Board of the SHC.

IV ELABORATION AND ARGUMENTATION

Keywords

Keywords	**Sleutelwoorden**	**Mots clés**	**Schlüsselwörter**
Prevention	Preventie	Prévention	Verhütung
Booster	Booster	Rappel (dose)	Booster
COVID-19	COVID-19	COVID-19	COVID-19
Vaccination	Vaccinatie	Vaccination	Impfung

List of abbreviations used

CHS	Clinical Hospital Surveillance
CI	Confidence Interval
COVID-19	Coronavirus disease 2019
ECDC	European Center for Disease Prevention and Control
EMA	European Medicines Agency
EUA	Emergency Use Authorizations
FDA	Food and Drug Administration
ICU	Intensive Care Unit
IMC	Interministerial Conference on Public Health
JCVI	Joint Committee on Vaccination and Immunisation
NPI	Non-pharmaceutical interventions
NITAG	National Immunization Technical Advisory Group
PCR	Polymerase Chain Reaction
SHC	Superior Health Council
VE	Vaccine effectiveness
WHO	World Health Organization

1 Effectiveness of COVID-19 Vaccination

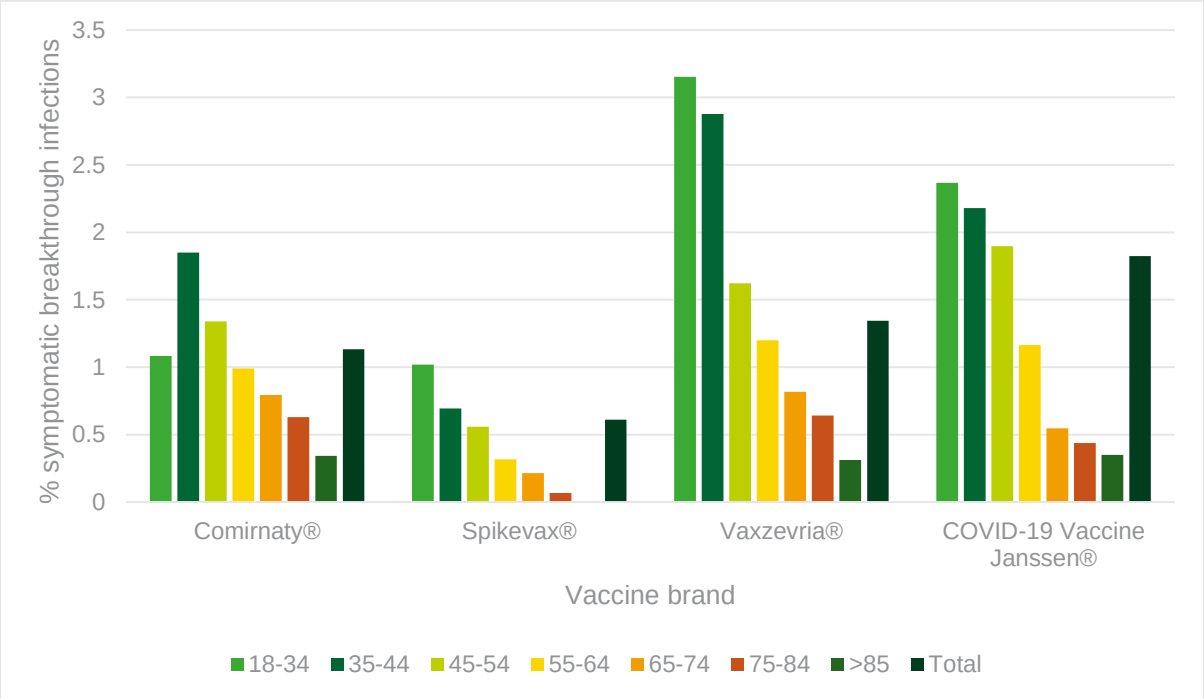
1.1 Effectiveness against (a)symptomatic COVID-19

1.1.1 Belgium (Sciensano)

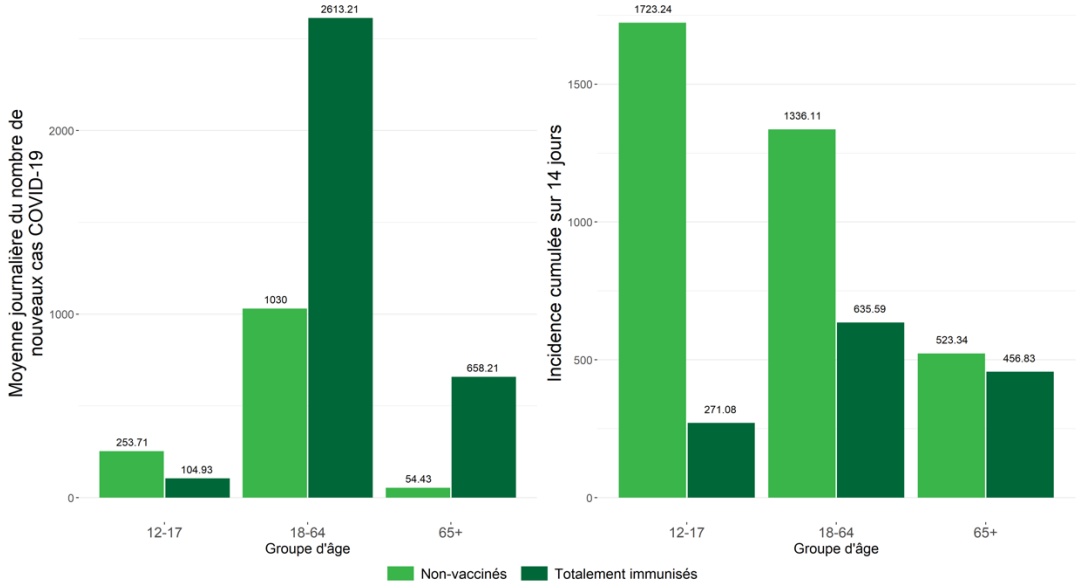
A breakthrough infection is defined as a new laboratory confirmed COVID-19 infection (positive RT-PCR or Rapid Antigen test; no positive test in prior 90 days) occurring in a fully immunized person. Fully immunized persons are those fully vaccinated for at least 14 days. Note that a person is considered as fully vaccinated after two doses of Comirnaty®, Spikevax® and Vaxzevria® vaccines or after a single dose of the COVID-19 Vaccine Janssen®.

As of 31 October 2021, out of a total of 8 493 907 fully immunized people aged 18 years and older, 1.27% (108 115) have tested positive for COVID-19 (RT-PCR or rapid antigen test) since the start of the vaccination campaign. Overall, infectious breakthroughs are rare, with a slightly higher frequency for those vaccinated with COVID-19 Vaccine Janssen® (2.13%; 8 357/392 731) compared to 1.23% (74 096/6 022 027), 0.96% (6 401/669 427) and 1.36% (19 210/1 408 055) for those vaccinated with Comirnaty®, Spikevax® or Vaxzevria® vaccine, respectively.

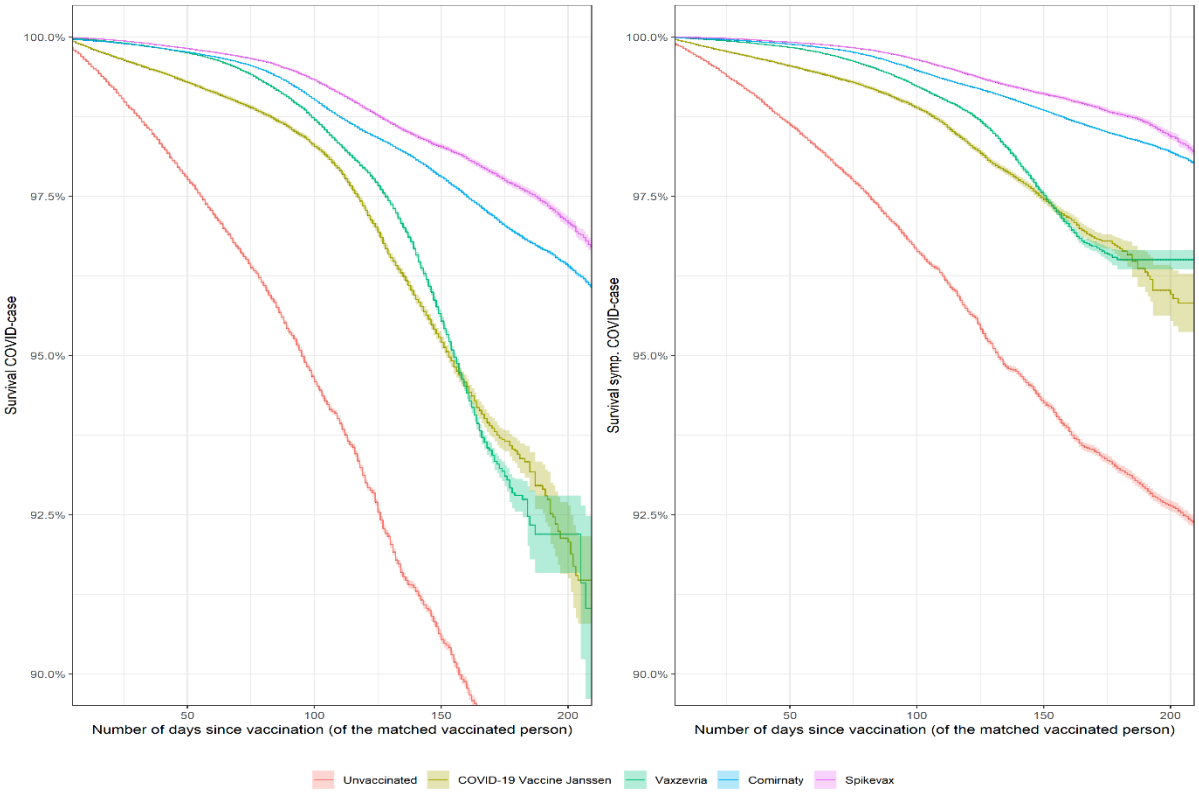
Based on the information on symptoms reported at the time of the call by contact tracing, about one third of the people detected with breakthrough infection did not have symptoms consistent with COVID-19 (28.46% (24 670/86 671)). This proportion of asymptomatic persons detected with COVID-19 is lower than in the overall population, regardless of vaccination status (37.7% (176 107/466 565) on 31/10/2021. This could be influenced by the testing strategy. In the figure below symptomatic breakthrough infections by brand of vaccine and age group are illustrated (figure by Sciensano).



The graphs here below show the daily average and 14-day cumulative incidence of the number of COVID-19 infections (symptomatic and asymptomatic), by vaccination status and age group, for the period 18 October 2021 to 31 October 2021. During this period, the majority of COVID-19 infections were detected in 18-64 year olds with a significant proportion detected in fully immunized individuals (defined as fully vaccinated + 14 days). However, the 14-day cumulative incidence is highest in non-vaccinated persons, for 12-17 year olds, followed by 18-64 year olds and finally 65+ year olds in whom the incidence of infection remains lower overall than in younger populations. Regardless of age, the incidence of infection is lower in fully immunized people compared to non-vaccinated people. In the period from 18 October to 31 October 2021, **the risk of infection in fully immunized people** aged 65 years and over, **18-64 years** and 12-17 years was reduced by 13%, **52%** and 84% respectively, compared to non-vaccinated people of the same age. Partially vaccinated persons or persons with unknown vaccination status are not included in these figures.



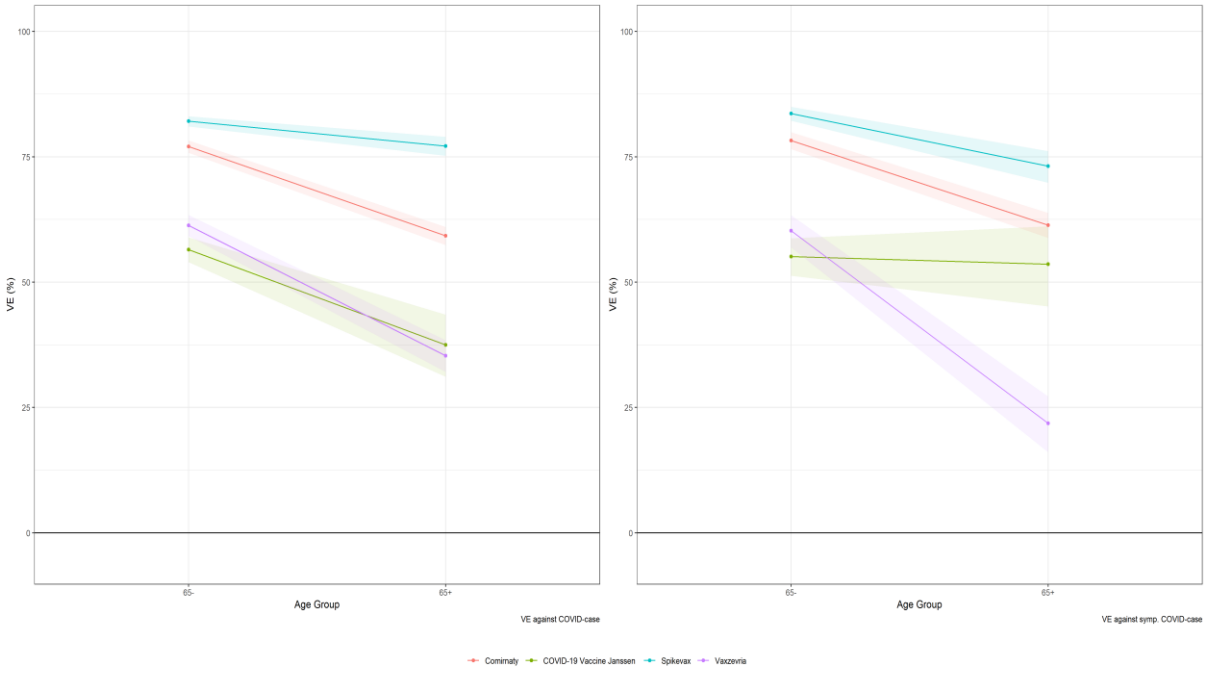
A Kaplan Meier survival analysis by Sciensano compared the probability of (symptomatic) infection over time among persons who have been fully immunized, between brands (figure below). The x-axis displays the number of days since vaccination, and the y-axis shows the percentage without an infection (left) or with a symptomatic infection (right). Curves that decline more rapidly represent a higher probability of developing a (symptomatic) infection.



All vaccine brands significantly protect against infection, compared to the unvaccinated, with the mRNA-vaccine, Comirnaty® and Spikevax®, providing the highest protection against infection. At 200 days after full immunization, the observed probability of having developed a breakthrough infection is less than 4% for both these brands, and less than 2% for developing a symptomatic infection over the study period (date of full vaccination to 14/11/2021). The probability of not developing a symptomatic infection in unvaccinated ones is 92% on a 200 days period.

For a more detailed investigation by vaccine brand, adjusting for age and moment of vaccination is necessary.

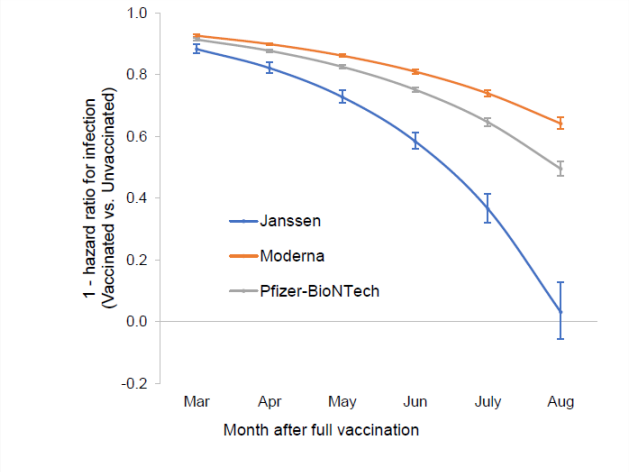
Vaccine effectiveness (VE) for (symptomatic) infection in < 65 years was estimated to be over 75% for Comirnaty® and Spikevax®, around 65% for Vaxzevria® and 55% for COVID-19 Vaccine Janssen®, aggregated over the study period (date of full vaccination to 14/11/2021). The graph on the left shows vaccine effectiveness against infection, the one on the right against symptomatic infection. For all vaccine brands, vaccine effectiveness against (symptomatic) infection is higher for those aged <65 years than for those aged ≥65 years.



1.1.2 International publications

Cohn et al. investigated breakthrough infections in 620 000 U.S. veterans. The proportionate reduction in infection associated with vaccination **declined for all vaccine types**, with the largest declines for Janssen followed by Pfizer-BioNTech and Moderna (figure below). **Patterns of breakthrough infection over time were consistent by age**, despite rolling vaccine eligibility, implicating the Delta variant as the primary determinant of infection (figure below - Cohn et al. 2021).

Figure 1. Time dependent vaccine protection against SARS-CoV-2 infection as estimated from Cox proportional hazards models, adjusted for age, race, ethnicity, sex and comorbidity Associations are presented as 1 – hazard ratios and 95% confidence intervals. Associations for each month were estimated from contrasts using product terms for vaccination status by time to most recent RT-PCR.



A preprint from the UK by Andrews et al. shows that vaccine effectiveness against **symptomatic disease** peaked in the early weeks after the second dose and then fell to 47.3% (95% confidence interval [CI] 45.0 to 49.6) and 69.7 (95% CI 68.7 to 70.5) by 20+ weeks against the Delta variant for Vaxzevria and Comirnaty, respectively. **Waning of vaccine effectiveness was greater for >65-year-olds compared to 40-64-year-olds.**

Table 1. Vaccine effectiveness against Delta symptomatic disease among individuals with two doses of Vaxzevria, Comirnaty or Spikevax in England at 1 week, 2-9 weeks, 10 -14 weeks, 15-19 weeks and 20+ weeks.

		Dose 2				
Vaccine	Age group	week 1	2-9 weeks	10-14 weeks	15-19 weeks	20+ weeks
Vaxzevria	16+	62.7 (61.7 to 63.8)	66.7 (66.3 to 67.0)	59.3 (58.8 to 59.9)	52.6 (51.7 to 53.5)	47.3 (45.0 to 49.6)
	65+	63.8 (48.2 to 74.8)	58.9 (54.8 to 62.6)	49.9 (45.4 to 54.0)	43.3 (38.1 to 48.0)	36.6 (28.7 to 43.7)
	40-64	57.1 (55.5 to 58.6)	63.6 (62.9 to 64.3)	59.8 (58.8 to 60.7)	56.9 (55.3 to 58.4)	57.8 (50.9 to 63.7)
	16-39	62.2 (52.5 to 70.0)	65.5 (60.9 to 69.5)			
Comirnaty	16+	92.4 (92.1 to 92.7)	89.8 (89.6 to 90.0)	80.3 (79.9 to 80.6)	73.4 (72.9 to 73.9)	69.7 (68.7 to 70.5)
	65+	65.4 (34.2 to 81.8)	80.1 (77.5 to 82.4)	69.1 (66.2 to 71.8)	62.1 (58.6 to 65.4)	55.3 (50.2 to 60.0)
	40-64	87.9 (86.1 to 89.4)	84.9 (84.3 to 85.4)	78.2 (77.5 to 78.9)	74.2 (73.1 to 75.3)	75.7 (71.1 to 79.5)
	16-39	92.5 (92.1 to 92.8)	91.0 (90.8 to 91.3)	77.1 (71.4 to 81.6)		
Spikevax	16+	95.2 (94.4 to 95.9)	94.5 (94.1 to 95.0)	90.3 (67.2 to 97.1)		
	40-64	94.0 (92.1 to 95.5)	93.7 (92.9 to 94.4)	96.1 (70.1 to 99.5)		
	16-39	95.0 (94.1 to 95.8)	94.9 (94.2 to 95.5)			

Nordstörm et al. showed in a retrospective cohort study including 842 974 matched pairs of vaccinated/unvaccinated individuals in Sweden that **vaccine effectiveness against symptomatic COVID-19 infection wanes progressively over time across all age groups**, but at a different rate according to the type of vaccine. Effectiveness against symptomatic infection peaked at day 15-30 (92%; 95% CI, 91%-93%, P<0.001) and declined marginally at day 31-60 (89%; 95% CI, 88%-89%, P<0.001). Effectiveness of Comirnaty® waned to 47% (95% CI, 39%-55%, P<0.001) at day 121-180, and no effectiveness was detected from day 211 and onwards (23%; 95% CI, -2%-41%, P=0.07). Waning was slightly slower for Spikevax®, with a remaining effectiveness of 59% (95% CI, 18%-79%, P<0.001) after more than 180 days of follow-up, and for heterologous Vaxzevria® / mRNA schedules (66%; 95% CI, 41%-80%, P<0.001 from day 121 and onwards - Nordstorm et al., 2021).

In Israel, Goldberg et al. compared rates of confirmed SARS-CoV-2 infection and severe COVID-19 among persons who received 2 doses of the Comirnaty® vaccine. **Immunity against the Delta variant of SARS-CoV-2 waned in all age groups** a few months after the second dose. Among persons 40 to 59 years of age, the rate ratio for infection among those fully vaccinated in February (when they were first eligible), as compared with 2 months later, in April, was 1.7 (95% CI, 1.4 to 2.1). Among persons 16 to 39 years of age, the rate ratio for infection among those fully vaccinated in March (when they were first eligible), as compared with 2 months later, in May, was 1.6 (95% CI, 1.3 to 2.0) (Goldberg et al., 2021).

A large retrospective cohort study in the U.S. found that VE of Comirnaty® against SARS-CoV-2 infections (all variants) declined from 88% (95% CI 86%-89%) during the first month after full vaccination to 47% (95% CI 43%-51%) after ≥ 5 months. Against Delta infections, VE was high during the first month after full vaccination (93% [95% CI 85%-97%]) but declined to 53% [95% CI 39%-65%] at ≥ 4 months (Tartof et al., 2021).

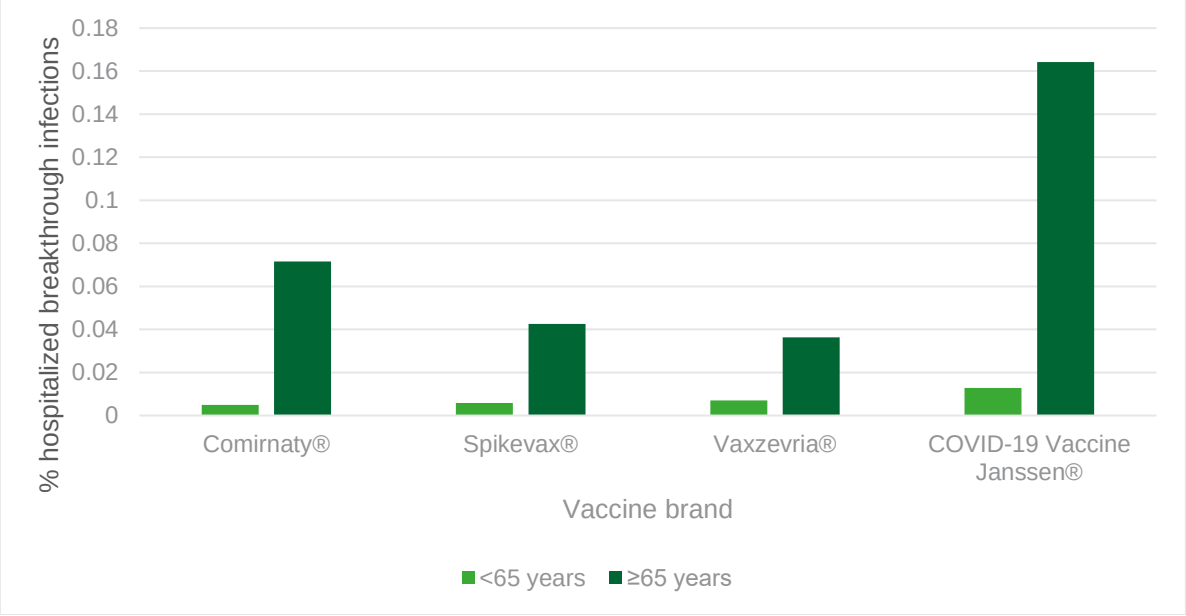
In a matched test-negative case-control study in Qatar, VE of Comirnaty® against any SARS-CoV-2 infection reached its peak at 77.5% (95% CI 76.4%-78.6%) in the first five weeks after the second dose and declined gradually thereafter, with the decline accelerating after the fourth month to reach approximately 20% in months 5 through 7 after the second dose. Effectiveness against symptomatic infection was higher than effectiveness against asymptomatic infection but waned similarly. Variant-specific effectiveness waned in the same pattern (Chemaitelly et al., 2021).

Waning of immunity has further been demonstrated in several studies assessing the evolution of SARS-CoV-2 antibodies since time of vaccination (Canaday et al., 2021; Pegu et al., 2021; Aldridge et al., 2021). For instance, a preprint study by Aldridge et al. investigated the variation in waning by vaccine type by measuring SARS-CoV-2 anti-S titers after BioNTech/Pfizer vaccination (N 3205) or AstraZeneca (N 5549) vaccination. At 20 weeks after the second dose of vaccine, the mean anti-S levels were 1521 (95% CI: 1432-1616) U/ml for BioNTech/Pfizer and 342 (95% CI: 322-365) U/ml for AstraZeneca. Aldrigde et al. identified 197 breakthrough infections and they found a reduced risk of infection post second dose of vaccine for individuals with anti-S levels greater than or equal to 500 U/ml compared to those with levels under 500 U/ml (HR 0.62; 95% CI: 0.44-0.87; p=0.007). An increased risk of a breakthrough infection for those who received the AstraZeneca vaccine compared to those who received the Pfizer BioNTech vaccine (OR: 1.43; 95% CI: 1.18-1.73; p<0.001). The authors conclude that **anti-S levels for both vaccines decline at similar rates,** suggesting the importance of booster doses and prioritizing individuals who received the AstraZeneca vaccine (Aldrigde et al., 2021).

1.2 Effectiveness of COVID-19 vaccination against severe infection, hospitalisation and death

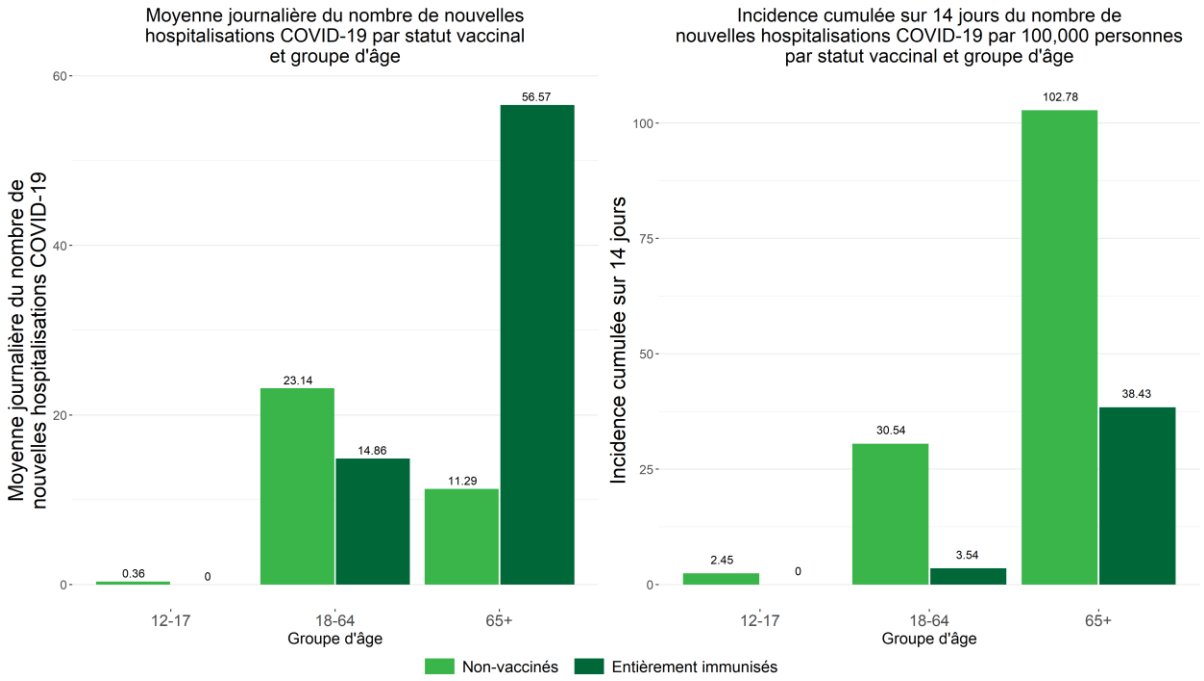
1.2.1 Belgium (Sciensano)

The proportions of hospitalized breakthrough infections among the total number of fully immunized persons, by vaccine brand and separate for the age groups <65 and ≥65 years, are displayed in the figure below. For all vaccine brands, proportions are higher among the ≥65 year age group, ranging from 0.036% for Vaxzevria®, to 0.164% for the COVID-19 Vaccine Janssen®. For the age group <65 years, the lowest proportion of hospitalized breakthrough infections is for Comirnaty® (0.005%) and the highest for the COVID-19 Vaccine Janssen® (0.012%). All proportions include also infections that have been detected after screening of patients that were admitted for other reasons, and as such also include asymptomatic cases.



1.2.1.1.Risk of hospitalization

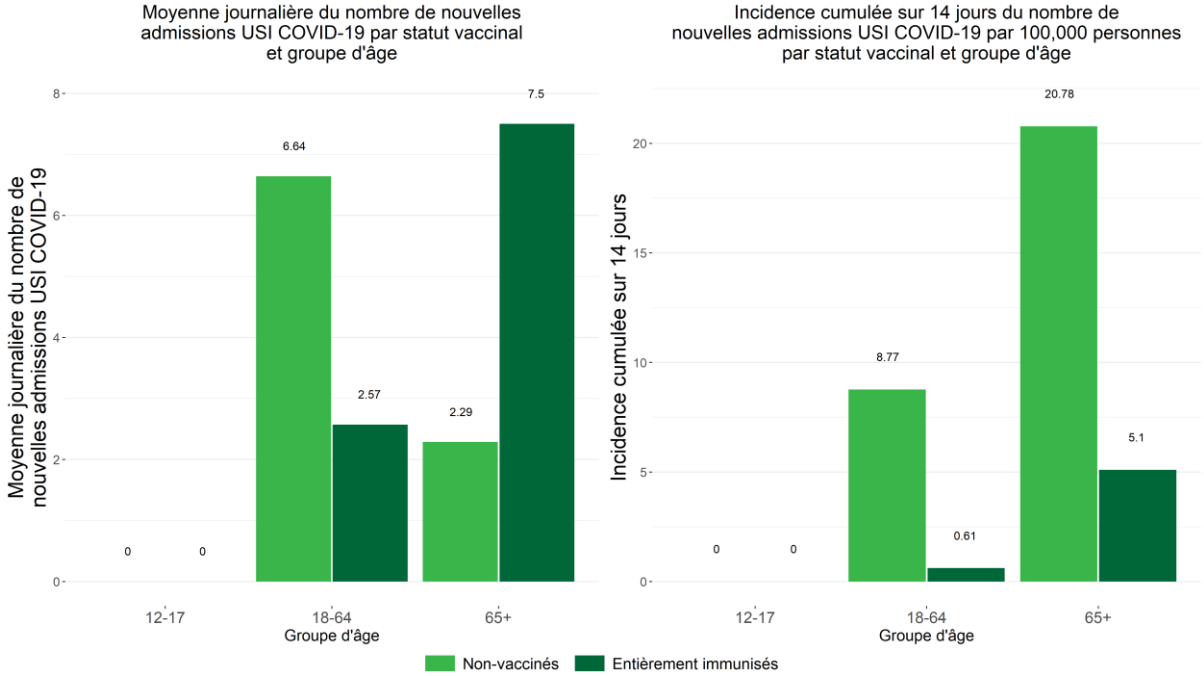
During the period from 18 to 31 October 2021, a total of 1 816 people were hospitalized for COVID-19 in Belgium. Of these, 565 were unvaccinated, 25 were partially vaccinated, 1000 were fully vaccinated and the vaccination status was not reported for 226 of them. The graphs below show the daily average and 14-day cumulative incidence of hospital admissions, by vaccination status and age group, for the period 18 October 2021 to 31 October 2021. Partially vaccinated persons or persons with unknown vaccination status are not included in these figures. These figures clearly illustrate the need to use incidences rather than proportions to show the impact of vaccination. For the same period, **the risk of hospitalization** for fully immunized people aged 65 years and over, **18-64 years** and 12-17 years was reduced by 63%, **88%** and 100% respectively, compared to non-vaccinated people of the same age.



Data from Surge capacity survey. As the time between vaccination and hospitalisation is not known in this survey using aggregated data, the 'fully immunised' group may include people who were fully vaccinated less than 14 days ago

1.2.1.2. Admission or transfer to an ICU

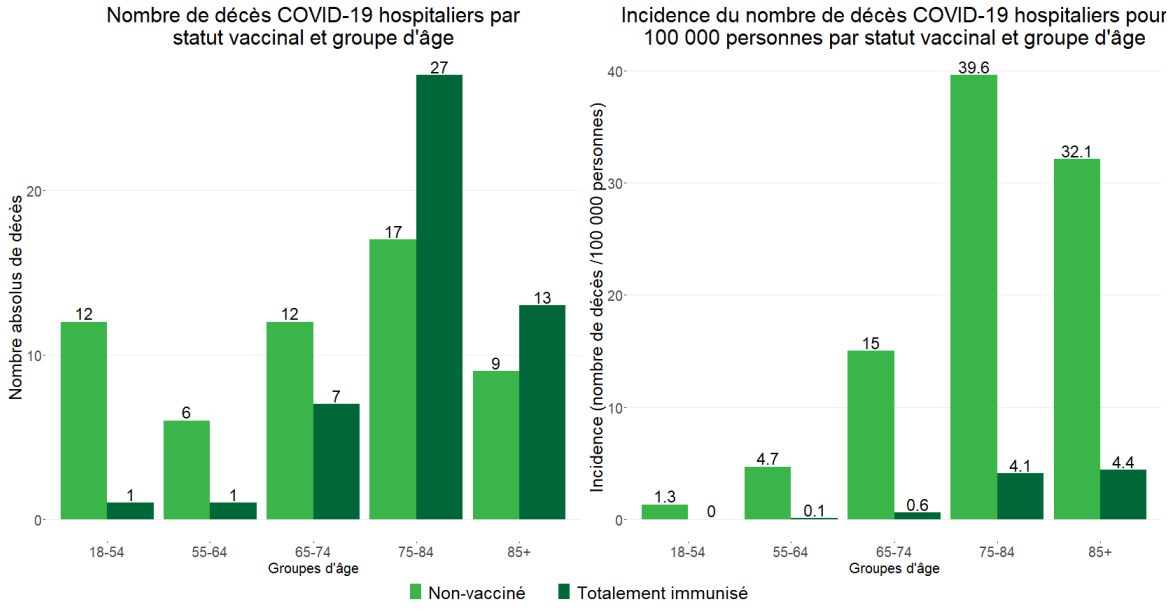
Among hospitalized COVID-19 patients, **admission or transfer to an ICU** is an indicator of disease severity. Thus, assessing the profile of COVID-19 patients admitted to ICUs in terms of vaccination status is an indicator of vaccine impact. During the period from 18 to 31 October 2021, a total of 324 people were admitted to ICUs due to COVID-19 in Belgium. Of these, 133 were unvaccinated, 4 were partially vaccinated, 141 were fully vaccinated, and the vaccination status was not reported for 46 of them. The risk of being admitted to an ICU increases with age. However, vaccination effectively reduces this risk. Indeed, as of 31 October, the risk of **ICU admission** for fully immunized individuals aged 65 years and over, **18-64 years** and 12-17 years was reduced by 75%, **93%** and 100% respectively, compared to non-vaccinated individuals of the same age.



Data from Surge capacity survey. As the time between vaccination and hospitalisation is not known in this survey using aggregated data,, the 'fully immunised' group may include people who were fully vaccinated less than 14 days ago

1.2.1.3. COVID-19 hospital deaths

The figure below shows the absolute numbers and incidence of **COVID-19 hospital deaths** by age group and vaccination status for the sample of hospital deaths between 6 September and 17 October 2021 recorded in the CHS (Clinical Hospital Surveillance), representing 31% of all hospital deaths during this period. Overall, among the population aged 18 years and older, the risk of dying from COVID-19 in hospital was 7.8 times lower for fully immunized patients than for unvaccinated persons. Among the older age groups, the risk of dying from COVID-19 was 7.3 and 12.2 times lower in fully immunized than in non-vaccinated individuals aged 85 years and over and 65-84 years, respectively. The risk of **dying during a hospital stay** due to COVID-19 in fully immunized patients aged 85 and over, 75-84, 65-74, **55-64, and 18-54 years** was reduced by 86%, 90%, 96%, **98% and 100%.**



1.2.2 International publications

Andrews et al. showed that VE fell less against **hospitalizations** to 77.0% (70.3% to 82.3%) and 92.7% (90.3% to 94.6%) beyond 20 weeks post-vaccination and 78.7% (95% CI 52.7% to 90.4%) and 90.4% (95% CI 85.1% to 93.8%) against death for Vaxzevria® and Comirnaty®, respectively. Greater waning was observed among >65-year-olds in a clinically extremely vulnerable group and 40-64-year-olds with underlying medical conditions compared to healthy adults (Andrews et al. 2021).

Tartof et al. found that VE **against hospital admissions** for infections with the Delta variant for all ages was high overall (93% [95% CI 84%-96%]) up to 6 months (Tartof et al., 2021).

In Qatar, Chemaitelly et al. found that VE against **any severe, critical, or fatal case** of COVID-19 increased rapidly to 66.1% (95% CI, 56.8% to 73.5%) by the third week after the first dose and reached 96% or higher in the first 2 months after the second dose; effectiveness persisted at approximately this level for 6 months (Chemaitelly et al., 2021).

In a study (preprint) by de Gier in the Netherlands **VE against hospitalization and ICU admission** didn't show waning with time up to 20 weeks after 2 dose vaccination (de Gier et al., 2021).

Nordström et al. found a **VE (any vaccine) against hospitalization and death** of 89% at day 15-30 (95% CI, 83%-93%, P<0.001), which declined to 74% (95% CI, 47%-87%, P<0.001) by day 121-180, **and from day 181 and onwards, there was no detectable associated effectiveness** (42%; 95% CI, -35%-75%, P=0.21) (table below - Nordström et al., 2021).

Supplemental Table 2. Vaccine effectiveness against Covid-19 hospitalization or death up to 9 months after full vaccination (>14 days after the second dose)

	Vaccinated		Unvaccinated		Vaccine effectiveness, % (95% CI)	
	No. of events	IR/100000 person-days	No. of events	IR/100000 person-days	Adjusted for age and baseline date	Fully adjusted*
15-30 days (N=1,685,948)	22	0·09	136	0·56	86 (78-91)	89 (82-93)
31-60 days (N=1,549,267)	65	0·13	354	0·89	88 (85-91)	91 (88-93)
61-120 days (N=1,341,155)	102	0·09	308	0·46	87 (84-90)	90 (87-92)
121-180 days (N=575,432)	27	0·03	21	0·08	79 (61-89)	74 (47-87)
>180 days (N=327,981)	61	0·10	6	0·07	20 (-80-75)	42 (-35-75)

*Adjusted for age, baseline date, sex, home maker service, place of birth, education, and comorbidities according to Table 1.

CI denotes confidence interval. IR denotes incidence rate.

A recent preprint study by Andrews et al. in the UK provides real world evidence of significant increased protection from **booster vaccine** dose **against symptomatic disease** in those aged **over 50 years old,** irrespective of which primary course was received (at least in short-term). VE of a Comirnaty® booster dose relative to those that had received only two doses was 87.4% (95% CI 84.9%-89.4%) where the primary course was Vaxzevria® and 84.4% (95% CI 82.8%-85.8%) where BNT162b2 was used as the primary course (table below - Andrews et al. 2021).

Table 2: Vaccine effectiveness against symptomatic disease for the BNT162b2 (Comirnaty, Pfizer-BioNTech) booster vaccine in England. Table values are VE (95% CI).

Primary Course (with second dose 140+ days before)	Interval since PF Booster	Controls	Cases	rVE (140+ days post dose 2 baseline)	rVE (dose 3: 2-6 days post booster baseline)	VE (unvaccinated baseline)
Unvaccinated	No booster	6303	7266			baseline
2AZ	No booster	83001	66433	Baseline		44.1 (41.9 to 46.1)
2AZ	0-1 days	694	611	-0.3 (-12.3 to 10.4)		44.9 (38 to 51)
2AZ	2-6 days	1328	1095	12.9 (5.3 to 19.9)	baseline	52.4 (47.9 to 56.5)
2AZ	7-13 days	1324	398	68.3 (64.4 to 71.7)	63.6 (58.1 to 68.3)	82.8 (80.6 to 84.7)
2AZ	14+ days	1128	138	87.4 (84.9 to 89.4)	85.5 (82.4 to 88.1)	93.1 (91.7 to 94.3)
2PF	No booster	57771	26735	Baseline		62.5 (61.0 to 63.9)
2PF	0-1 days	1422	758	-7.1 (-17.5 to 2.4)		59.5 (55.3 to 63.3)
2PF	2-6 days	3167	1525	9.9 (3.8 to 15.7)	baseline	65.8 (63.2 to 68.2)
2PF	7-13 days	4025	719	68.3 (65.5 to 70.8)	64.8 (61 to 68.2)	87.9 (86.7 to 88.9)
2PF	14+ days	5387	518	84.4 (82.8 to 85.8)	82.6 (80.6 to 84.5)	94.0 (93.4 to 94.6)

Bar-on et al. (Israel) showed that the rate of **confirmed infection** was lower in the booster group than in the non-booster group by a factor of 11.3 (95% CI, 10.4 to 12.3) for persons who were **60 years of age or older** (table below - Bar-on et al.2021).

Table 2. Primary Outcomes of Confirmed Infection and Severe Illness.*

Outcome	Nonbooster Group	Booster Group	Adjusted Rate Ratio (95% CI)†
Confirmed infection			11.3 (10.4–12.3)
No. of cases	4439	934	
No. of person-days at risk	5,193,825	10,603,410	
Severe illness			19.5 (12.9–29.5)
No. of cases	294	29	
No. of person-days at risk	4,574,439	6,265,361	

* Listed are the results of the Poisson regression analysis in participants who received a booster vaccine and in those who did not receive a booster. The booster group includes data that were obtained at least 12 days after receipt of the booster dose.

† The rate ratio is the estimated factor reduction in the rate in the booster group as compared with the rate in the non-booster group.

Barda et al. evaluated VE at least 7 days after receiving the third dose, compared to having received only two doses at least 5 months ago. It was estimated to be 93% (231 events for two doses vs 29 events for three doses; 95% CI 88%-97%) for admission to hospital, 92% (157 vs 17 events; 95% CI 82%-97%) for severe disease, and 81% (44 vs 7 events; 95% CI 59%-97%) for COVID-19-related death (table below - Barda et al. 2021).

	Total number in analysis (both study groups combined)	Vaccinated with two doses		Vaccinated with three doses		1–risk ratio (95% CI)	Risk difference per 100 000 individuals (95% CI)
		Events	Risk per 100 000 individuals	Events	Risk per 100 000 individuals		
Admissions to hospital							
Sex							
Male	458 552	140	321·6	21	25·2	92% (85 to 97)	296·4 (177·2 to 443·2)
Female	483 548	91	132·1	8	5·0	96% (93 to 99)	127·1 (87·2 to 175·9)
Age group, years							
16–39	288 072	6	7·0	1	2·1	70% (–70 to 100)	4·9 (–2·1 to 12·3)
40–69	448 366	73	104·9	10	8·1	92% (83 to 97)	96·7 (60·1 to 148·7)
≥70	162 958	140	574·3	16	41·3	93% (87 to 97)	533·0 (390·1 to 675·3)
Number of coexisting conditions							
0	462 690	14	13·4	2	1·5	89% (60 to 100)	11·9 (4·3 to 22·3)
1–2	336 850	61	111·5	7	9·7	91% (80 to 98)	101·9 (61·9 to 145·9)
≥3	142 560	156	689·7	20	56·3	92% (87 to 96)	633·4 (456·4 to 847·7)
Severe disease							
Sex							
Male	458 652	103	233·0	13	24·8	89% (73 to 98)	208·2 (109·7 to 343·9)
Female	483 614	54	93·2	4	2·8	97% (93 to 99)	90·4 (57·4 to 137·8)
Age group, years							
16–39	288 086	2	2·5	0	0·0	NA	2·5 (0·7 to 7·5)
40–69	448 410	38	57·9	5	3·5	94% (85 to 99)	54·4 (28·0 to 87·6)
≥70	163 054	108	447·5	10	35·8	92% (83 to 98)	411·7 (285·9 to 548·7)
Number of coexisting conditions							
0	462 706	5	3·1	0	0·0	NA	3·1 (0·7 to 6·0)
1–2	336 902	39	82·0	2	3·2	96% (85 to 100)	78·8 (39·3 to 126·8)
≥3	142 658	113	503·5	15	51·6	90% (80 to 96)	451·9 (322·3 to 605·2)

Estimates were obtained using the Kaplan-Meier estimator starting from day 7 after receipt of the third dose in those who received it. Data are listed as NA when one or both of the study groups do not have any events. NA=not available.

Table 3: **Subgroup analysis of the effectiveness of the third vaccine dose versus two vaccine doses of the BNT162b2 mRNA COVID-19 vaccine**

Gardner et al. found that a third dose could substantially reduce transmission, especially in highly vaccinated populations, and the effect was larger in populations with lower acquired immunity from infection and when contact rates were higher (Gardner et al., 2021).

At this moment, data are scarce on the effect of a booster dose of COVID-19 vaccination on vaccine-induced immunity and duration of protection against severe outcome and (symptomatic) infection of COVID-19.

Based on international preprint studies and data from Sciensano, protection against (a)symptomatic infection seems to wane more rapidly over time compared to protection against serious disease or mortality.

This trend occurs more rapidly in older individuals who also completed their primary vaccination earlier.

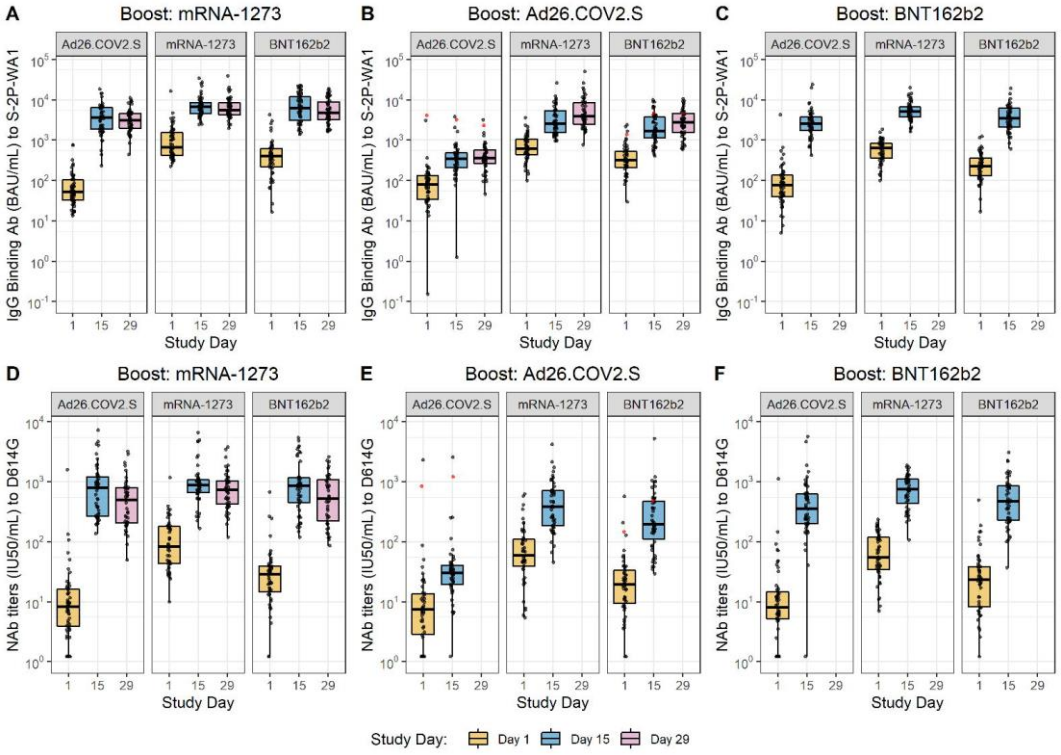
1.2.3 Booster vaccination

The Food and Drug Administration (FDA) decided on October 20 2021 that a single booster dose of the COVID-19 Vaccine Janssen® (Johnson and Johnson) may be administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older.

On November 19 2021, the FDA amended the emergency use authorizations (EUA) for both the Moderna and Pfizer-BioNTech COVID-19 vaccines authorizing the use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine.

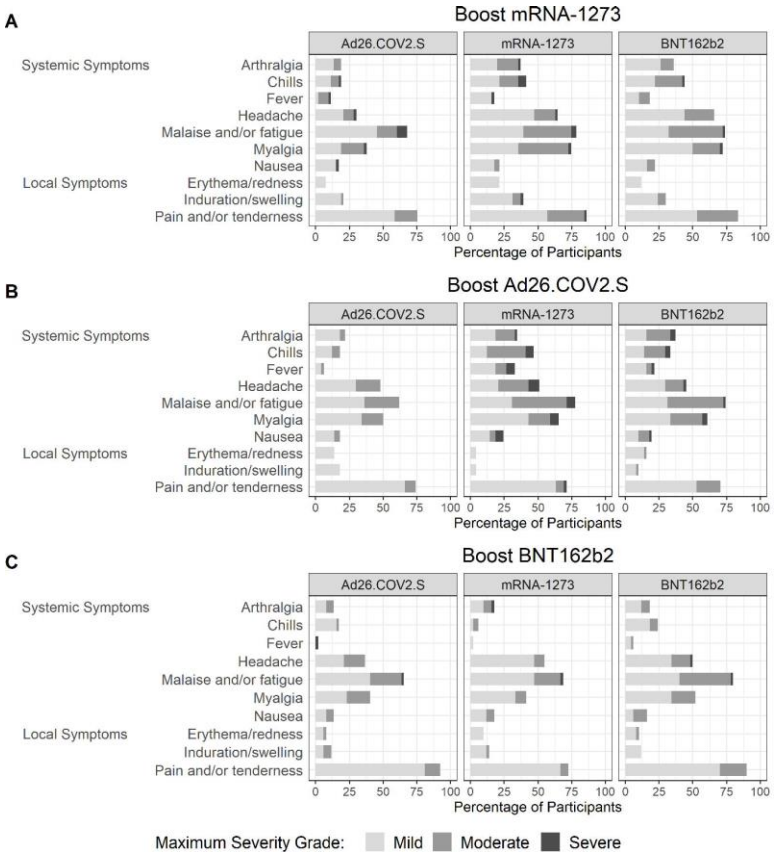
The decision of the EMA on booster doses is still pending.

A preprint study by Atmar et al. showed that the increases from baseline in both binding and neutralizing antibody titers were similar or greater after heterologous boosts compared to homologous boosts (figure below - Atmar et al., 2021).



1.2.4 Safety and reactogenicity of a heterologous booster

Reactogenicity of a heterologous booster was similar to that described in prior evaluations of COVID-19 Vaccine Janssen®, Spikevax® and Comirnaty® vaccines (figure below - Atmar et al., 2021).



In contrast, Shaw et al. found an increase in systemic reactogenicity after the booster dose reported by participants in heterologous vaccine schedules in comparison to homologous vaccine schedules. Compared with homologous vaccination, heterologous boosters induced higher rates of fever (Shaw et al., 2021).

2 Country experience on booster recommendations

Israel was the first country recommending a booster dose of the Pfizer vaccine for all citizens older than 12.

The ECDC (European Center for Disease Prevention and Control) published on November 11 2021 the report 'Overview of the implementation of COVID-19 vaccination strategies and deployment plans in the EU/EEA'.
https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-vaccination-strategies-and-deployment-plans-Nov-2021.pdf
In table 8 of this document, an overview is made with details of recommendations for an additional and/or booster dose in 30 countries.

On November 15 2021, the Joint Committee on Vaccination and Immunisation (JCVI) announced that booster COVID-19 vaccine shots with mRNA will be extended to 40-49 year-old individuals in the UK, 6 months after their second dose. Based on the collected data about the durability of protection in this age group (irrespective of the vaccines given for the first and second doses), the JCVI advises that booster vaccination should be offered to those persons to maintain protection against serious disease and mortality (JCVI, 15 Nov 2021).

The ECDC published on November 24 2021 a report stating: *"Modelling forecasts highlight the need for Non-Pharmaceutical Interventions (NPIs) as an immediate measure to control transmission, in combination with roll-out of vaccine booster doses for adults, which should be prioritized for those aged 40 years and over, at least six months after completing a primary vaccine schedule. Booster doses will sustain transmission control beyond the immediate impact of implementing NPIs."*
https://www.ecdc.europa.eu/en/publications-data/rapid-risk-assessment-sars-cov-2-situation-november-2021

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VI COMPOSITION OF THE WORKING GROUP

The composition of the Committee and that of the Board as well as the list of experts appointed by Royal Decree are available on the following website: About us.

All experts joined the working group ***in a private capacity***. Their general declarations of interests as well as those of the members of the Committee and the Board can be viewed on the SHC website (site: conflicts of interest).

Based on the discussions and conclusions of the NITAG meeting on November 18 2021, this advisory report was drafted and send for approval to NITAG by email. The following experts participated at the NITAG meeting and/or approval of the report. The NITAG meeting was chaired by **Yves VAN LAETHEM**; the scientific secretariat were Veerle MERTENS, Fabrice PETERS, Muriel BALTES and Jean-Jacques DUBOIS.

BEUTELS Philippe	Health Economics	UAntwerpen
BLUMENTAL Sophie	Pediatric Infectious Disease	HUDERF
BOIY Tine	Pediatrics	UZA
BRASSEUR Daniel	Pediatrics	ULB
CALLENS Steven	Infectiology, Internal medicine	UZ Gent
CARILLO SANTISTEVE Paloma	General medicine, vaccination	ONE
CHATZIS Olga	Pediatrics, Vaccinology	UCL
CORNELISSEN Laura	Epidemiology, Obstetrics, Gynaecology	Sciensano
DE LOOF Geert	General medicine	BCFI
DE SCHEERDER Marie-Angélique	Internal medicine, Infectiology, Travel clinic, HIV	UZ Gent
DOGNE Jean- Michel	Farmacovigilance	UNamur, EMA
DONDERS Gilbert	Gynaecology	RZ Tienen
FRERE Julie	Pediatrics, Infectiology	CHU Liège
GOVAERTS Frans	General medicine, Prevention and health promotion	Domus Medica
HULSTAERT Frank	Epidemiology, Health Economics	KCE
LEROUX-ROELS Isabel	Vaccinology, Infection prevention, Microbiology	UZ Gent
MALFROOT Anne	Pediatrics, Infectiology	UZ Brussel
MANIEWSKI Ula	Infectiology, Tropical infectious diseases, Vaccinology	ITG-IMT
MICHIELS Barbara	General medicine	UAntwerpen
PELEMAN Renaat	Infectiology, Vaccinology	UZ Gent
ROBERFROID Dominique	Epidemiology	KCE, UNamur
ROSSI Camelia	Infectiology, internal medicine	CHU Ambroise Paré
SCHELSTRAETE Petra	Pediatrics, Pneumology, Vaccinology	UZ Gent
SMEESTERS Pierre	Pediatrics	HUDERF
SOENTJENS Patrick	Internal medicine, Tropical infectious diseases	ITG - Defence
SPODEN Julie	General medicine	SSMG
SWENNEN Béatrice	Epidemiology, Vaccinology	ULB
TILMANNE Anne	Pediatrics, Infectiology	CHU TIVOLI
TUERLINCKX David	Pediatrics, Vaccinology	CHU UCL Namur
VERHAEGEN Jan	Microbiology, Bacteriology	UAntwerpen

VAN DER LINDEN Dimitri	Pediatrics, Infectiology	UCLouvain
VAN DAMME Pierre	Epidemiology, Vaccinology	UAntwerpen
VAN LAETHEM Yves	Infectiology, Vaccinology, Travel medicine, HIV	CHU Saint-Pierre, ULB
VANDEN DRIESSCHE Koen	Pediatrics, Immunology, Pneumology	UZA
WYNDHAM-THOMAS Chloé	Epidemiology, Infectiology	Sciensano

The following experts/administrations were heard but did not take part in endorsing the advisory report:

DAEMS Joël	RIZIV-INAMI
MAHIEU Romain	CCC-GGC, Directorate for Health
MALI Stéphanie	AFMPS-FAGG
THEETEN Heidi	Agentschap Zorg en Gezondheid
TOP Geert	Agentschap Zorg en Gezondheid
WUILLAUME Françoise	AFMPS-FAGG

About the Superior Health Council (SHC)

The Superior Health Council is a federal advisory body. Its secretariat is provided by the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides scientific advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC aims at giving guidance to political decision-makers on public health matters. It does this on the basis of the most recent scientific knowledge.

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, staff members of scientific institutions, stakeholders in the field, etc.), 300 of whom are appointed experts of the Council by Royal Decree. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, and a Committee on Professional Conduct) as well as the final endorsement of the advisory reports by the Board (ultimate decision-making body of the SHC, which consists of 30 members from the pool of appointed experts). This coherent set of procedures aims at allowing the SHC to issue advisory reports that are based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

Once they have been endorsed by the Board, the advisory reports are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.hgr-css.be). Some of them are also communicated to the press and to specific target groups (healthcare professionals, universities, politicians, consumer organisations, etc.).

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