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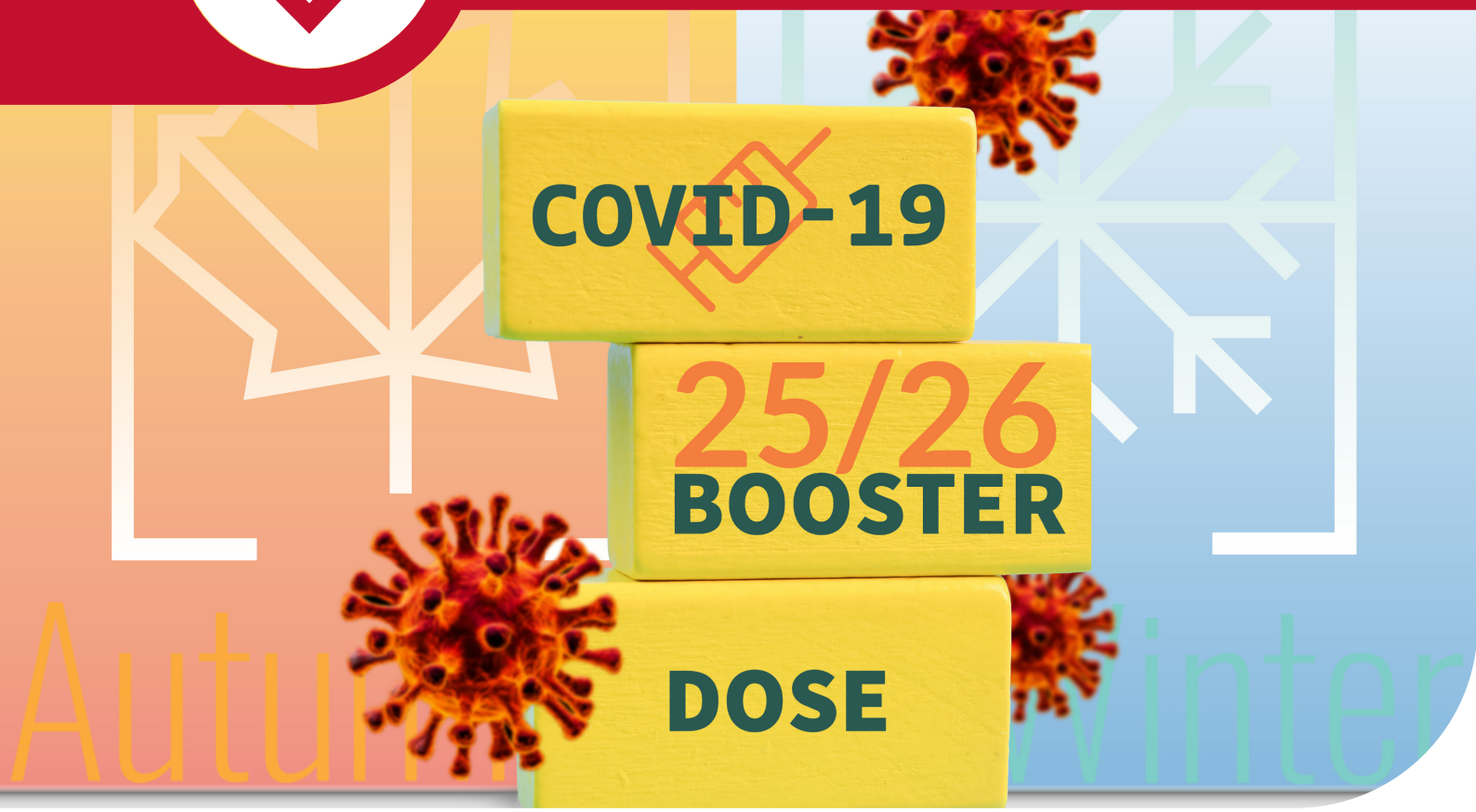

COVID-19 - Belgian vaccination strategy (2025-2026)

Juli 2025

No. 9880

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Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL no. 9880

COVID-19 - Belgian vaccination strategy - 2025-2026

In this scientific advisory report, which offers guidance to public health policy-makers, the Superior Health Council of Belgium provides an update of the COVID-19 vaccination strategy with adapted to circulated strains vaccines (EMA, 17/05/2025) for the Belgian priority groups, pregnant women included during the season 2025-2026.

First conclusions and recommendations approved by the members of the NITAG on 19 June 2025
Approval of this full version of the advisory report by the NITAG by mail
Advisory report validated by the Board on 2 Juli 2025[1]

I INTRODUCTION AND ISSUE

As in the case of influenza vaccination, each year the National Immunization Technical Advisory Group (NITAG) of the Superior Health Council (SHC) reassesses its annual recommendations on winter vaccination strategy in Belgium.

As for the 2023 and 2024 seasons, and in association with the Belgian Society of Intensive Care Physicians (SIZ) and the Belgian Respiratory Society (BeRS), the Council insists on achieving **the highest possible** vaccination coverage in Belgium for people over 65 against Coronavirus disease 2019 (COVID-19), seasonal influenza, pneumococcal infections and Respiratory Syncytial Virus (RSV)[2]. This approach is also encouraged by some authors in the recent literature (Torres et al., 2025; Reynard et al., 2024; Wang et al., 2024).

On 17/05/2025, the European Medicines Agency (EMA) recommends updating the antigenic composition of authorized COVID-19 vaccines for the 2025-2026 vaccination campaign. This is due to the continuous emergence of new SARS-CoV-2 variants driven by immune evasion and viral fitness. While current vaccines are effective against severe disease, their protection can decrease as the virus evolves into more antigenically distant variants. Matching vaccine content to circulating viruses improves protection. The EMA's Emergency Task Force (ETF) specifically recommends adapting vaccines to target the LP.8.1 variant of the JN.1 family of Omicron subvariants. This is because LP.8.1 appears to have the greatest growth advantage and increased transmissibility, and exhibits strong humoral immune evasion compared to other emerging variants. Both XEC and LP.8.1 variants belong to the BA.2.86 family of Omicron subvariants, which is antigenically distant from the XBB family circulating in 2023 and previous variants. LP.8.1 has become dominant in various parts of the world, including the United States of America (USA), and is spreading in Europe.

[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.

[2] Bescherm jezelf deze winter : meerdere vaccinaties tegen luchtweginfecties voor 65-plussers - Hoge Gezondheidsraad (hgr-css.be)
Protégez-vous cet hiver : pluri-vaccination respiratoire pour les + de 65 ans - Conseil Supérieur de la Santé (hgr-css.be)

Vaccines targeting JN.1 or KP.2 strains can still be used for the 2025 campaigns until LP.8.1 vaccines become available. The communication about this is very important for the vaccinators and the general population.

The Variants Of Concern (VOC)-adapted COVID-19 vaccines considered in this report are the mRNA-adapted vaccines Comirnaty®, Spikevax® and the recombinant, adjuvanted vaccine Nuvaxovid®. If not specified in the report, the Council always refers to the EMA and the Belgian Federal Agency for Medicines and Health Products (FAMHP) recommendations regarding the dosage, the schedule and the route of administration of the vaccines.

At the time of the publication of this advice, the SHC is aware that several companies are actively developing combined influenza and COVID-19 vaccines intended for the European market. As the regulatory process is still ongoing, these combination vaccines are not expected to be available for the 2025–2026 season (Rudman et al., 2025; Choi et al., 2024).

Further information (European Public Assessment Report - EPAR)
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty
https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax
https://www.ema.europa.eu/en/medicines/human/EPAR/nuvaxovid

As with the annual influenza vaccination with vaccines adapted to circulating strains, it is not anticipated that a large amount of clinical efficacy data in real life of vaccines adapted to current and future strains **will be available at the time of recommendation and administration**. At the time of drafting these recommendations for the 2025-2026 season, the SHC did not observe major changes in the Belgian epidemiological data and did not find major and concordant scientific publications **that could drastically change the already proposed vaccination strategy in 2024-2025**. The elements that could require a rapid and urgent adaptation of these recommendations and of the vaccination campaign in Belgium for 2025-2026 would be:

- **new adapted vaccines** with longer or broader protection;
- the arrival of a **new VOC** with massive immune escape;
- a **drastic loss of vaccine efficacy (VE)** on hospitalizations and deaths; it remains important to continue regular monitoring of the profiles of patients who die or are admitted to hospital with COVID-19 according to their vaccination status, comorbidities, immunosuppressive treatments, etc. in Belgium, abroad and according to any new variants;
- a **global shift in international recommendations towards more frequent and regular boosters**;

II RECOMMENDATIONS

1 Main Objective

As for the 2023-2024 season, and in association with the SIZ and the BeRS, the Council insists on achieving the highest possible vaccination coverage in Belgium for people over 65 against Coronavirus disease 2019 (COVID-19), seasonal influenza, pneumococcal infections and Respiratory Syncytial Virus (RSV).

2 Risk groups for Autumn / Winter season 2025 – 2026 COVID-19 vaccination (no changes compared to 2024-2025 season)

At present, **the target groups for vaccination against seasonal influenza and COVID-19 are similar**, which greatly simplifies simultaneous administration of the two vaccines.

Highlighted in yellow are the elements that differ from those established for seasonal flu vaccination

In order to best anticipate the next COVID-19 vaccination campaign in Belgium, the SHC recommends the administration of an additional VOC-adapted COVID-19 vaccine for:

- **Group 1**: people at increased risk of death or severe forms of the disease because of either advanced age (≥65y) or comorbidities.
- **Group 2**: all persons active in the care sector.
- **Group 3**: all persons living under the same roof as (very) severely immunocompromised patients.

A detailed description of the different groups is listed below.

For people aged 18 to 65y old and not included in groups 1, 2 or 3, vaccination can be proposed on an individual basis, after consultation with their physician and taking into account other risk factors.

At present, routine COVID-19 vaccination is not recommended for healthy children and adolescents.

Group 1: people with increased risk of death or severe forms of the disease (hospitalization, ICU and death)

- Any person aged **65 years and over** (similar to seasonal flu vaccination);
- Any person **living in LTCF and nursing homes** (similar to seasonal flu vaccination);
- **Pregnant women**, at any stage of pregnancy, **with comorbidities** OR expected to have a high-risk pregnancy OR not yet infected/vaccinated;
- Any person **with a BMI ≥ 40 kg/m2** (similar to seasonal flu vaccination);
- Any patient aged 18 years or over **with at least one comorbidity** (Ganaza-Domingues et al., 2025) - underlying chronic condition, even if stabilized of
    - **pulmonary origin** such as bronchiectasis, chronic obstructive pulmonary disease (COPD), interstitial lung disease, pulmonary embolism, pulmonary hypertension, tuberculosis, etc., including severe asthma[3] and cystic fibrosis (Shahrebabak et al., 2025) - similar to seasonal flu vaccination;
    - **hepatic origin** such as cirrhosis, non-alcoholic fatty liver disease, alcoholic liver disease, autoimmune hepatitis, etc. (De Simone et al., 2025) - similar to seasonal flu vaccination;
    - **renal origin** and people receiving dialysis (Hachimi et al., 2025) - similar to seasonal flu vaccination;
    - **metabolic origin**, including diabetes type 1 and 2 (Attia et al., 2024) - similar to seasonal flu vaccination;
    - **cardiac origin** (Heidecker et al., 2025) such as heart failure, coronary artery disease, cardiomyopathies, cerebrovascular disease - similar to seasonal flu vaccination, **including hypertension with cardiac complications (mixed evidence)**. At this stage, no definitive conclusions can be drawn from the evidence for hypertension alone and the risk of severe COVID-19 (CDC, 09/02/2023; Therre et al., 2025; Ashmawy et al., 2025; de Souza et al., 2025);
    - **neurologic origin, severe mental health conditions and severe intellectual disability** such as dementia, severe depression, schizophrenia spectrum disorders, etc. (Jia et al., 2024).
- **Certain patients with rare diseases** (including Down syndrome with associated comorbidities or immunological impairment). We would like to emphasize that the group for which the rare disease has an impact on cardiovascular, respiratory or neurological health is given special attention. In order to know the rare diseases mainly considered, please refer to the Orphanet list. https://www.orpha.net/consor/cgi-bin/Disease_Search_List.php?lng=EN

[3] According to the criteria of the Global Initiative for Asthma (GINA). Severe asthma is defined as asthma that requires treatment with high-dose inhaled corticosteroids plus a second control agent (and/or systemic corticosteroids) to prevent it from becoming "uncontrolled" or remains "uncontrolled" despite such treatment".

- **Any patient aged 18 years or over with immunosuppression due to disease or treatment** (SHC 9691, 03/03/2022) - similar to seasonal flu vaccination:

    - **with an organ or a stem cell transplant** - pre-transplant included (Foroutan et al., 2025; Rayner et al., 2024; Hua et al., 2024);

    - **who are on immunomodulating drugs** (Kontandreopoulou et al., 2024; Ammitzbøll et al., 2025; Rivera-Izquierdo et al., 2024; Bianchi et al., 2024);

    - **who are undergoing cancer treatment or have been treated in the last 3 years**;

    - **with primary immune deficiency** (patients with Down syndrome included);

    - **with Human Immunodeficiency Virus (HIV) infection and low CD4 counts** < 200 /mm³ (Xu et al., 2025).

Remark (cf. appendix 1 for details): the specific situation of IC patients and the corresponding risk of infection **can change in the course of treatment**. Individual patients can move between risk groups depending on their clinical treatment situation (e.g. induction vs. consolidation therapy, recurrence of leukaemia, preparation for and execution of stem cell transplantation after conventional treatment). **This means that it may be necessary for physicians to amend the risk evaluation in their risk analysis and to recommend the vaccination**.

- **Children and adolescents till 18 years** (SHC 9722, 2022), with immunosuppressive treatment, some auto-immune disease, haemato-oncological disease, with some primary immunodeficiencies (PID), severe chronic diseases affecting renal, gastro intestinal, cardiovascular, respiratory or neurological health and certain rare conditions including Down syndrome with associated comorbidities or immunological impairment (cf. appendix 2 for details).

Group 2: all "persons active in the care sector", in and outside care institutions - similar to seasonal flu vaccination

Vaccinating care workers serves 3 purposes:

- individual protection against severe disease;
- minimize as much as possible the risk of transmission to the most vulnerable patients;
- ensure maximum functioning of the overall health care sector during the critical winter period (Reichert et al., 2022; Pitak-Arnnop et al., 2024).

The SHC reiterates however that the duration of protection against infections and transmission by vaccination, in the context of Omicron, is lower than protection against severe forms of the disease and declines over time (IgG still there after 9 month, Dodge et al., 2025). **This vaccination strategy thus complements but does not replace non-pharmaceutical interventions (NPIs)**.

The term "persons active in the care sector" covers all the socio-professional categories listed in the SHC 9597 and 9611 of September 2020. This group "people active in the care sector" includes all people involved and active (including volunteers and trainees).
https://www.health.belgium.be/fr/avis-9597-strategie-de-vaccination-covid-19

Group 3: all persons living in the same household as (very) severely immunocompromised patients.

A "COVID-19 cocoon" vaccination strategy is recommended for all persons living in the same household as severely and very severely immunocompromised patients (defined as KRINKO risk groups 2&3, see appendix 1).

Even though protection against infection with Omicron wanes over time, the SHC would like to minimize the risk of transmission to the most vulnerable patients. The SHC reiterates that cocoon vaccination strategy complements but does not replace non-pharmaceutical interventions (NPIs) for people at risk of severe disease (Kampf et al., 2024).

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Additional risk factors that could be taken into account to prescribed COVID-19 vaccination on an individual basis and in consultation with the physician.

A) persons aged 50-64 years old, especially if the present multiple risk factors

- current (or former) smoking

At least three major systematic reviews and meta-analyses (Reddy et al., 2021; Sanchez-Ramirez and Mackey, 2020; Patanavanich and Glantz, 2020) have shown **that smoking (current or former smokers) approximately doubles the risk of serious complications from COVID-19**. Significant RR ranged from 1.26 to 3.46, depending on smoking status and the different outcomes measured. This is confirmed by other systematic reviews all around the world (Vardavas et al., 2020; Zhao et al., 2020; Zhang et al., 2022; Zheng et al., 2020; Lippi et al., 2020; Guo, 2020; Alqahtani et al., 2020; Li et al., 2021; Farsalinos et al., 2020). To our knowledge, there are as yet no VE data published specific to smokers and for the Omicron period**.** Nevertheless, vaccination should reduce the risk for these people too.

- **physical inactivity** (Hill et al., 2021; Arena et al., 2024)

Twenty-five studies, 15 cohort, 5 cross-sectional, 4 ecological and one case-control, reported data on physical inactivity or physical activity and severe COVID-19 outcomes and were included in this analysis. The data indicate an association between increased mortality and hospitalization due to COVID-19 infection and physical inactivity, and a possible association between increased ventilation due to COVID-19 infection and physical inactivity. Limited data is insufficient on the association between physical inactivity and ICU admission. Limited data from only one study is insufficient to determine if there is an association between physical inactivity and intubation. **Nevertheless, the data suggest an increased risk of mortality and hospitalization due to COVID-19 infection with decreased duration or frequency of physical activity**. To our knowledge, there are as yet no VE data published specific to physical inactivity and for the Omicron period. **Nevertheless, vaccination should reduce the risk for these people too** (CDC).

- excessive use of alcohol (SHC 9438, 2018; Pavarin et al., 2022)

The causal link between alcohol consumption and infectious diseases is uncertain, but it is now generally accepted that alcohol consumption is associated with tuberculosis, HIV/AIDS, other sexually transmitted infections and pneumonia. These links are clear in cases of high alcohol consumption, however, the existence of a threshold below which there would be no risk is still uncertain (SHC 9781, 2024). Several authors draw attention to the risk of alcohol consumption (and other precarious factors) for severe forms of COVID-19 (Ostinelli et al., 2022; Webb et al. 2020; Tsai et al., 2020; McCosker et al., 2025), but few standardized studies are available to our knowledge. Chronic liver diseases (cirrhosis, alcoholic liver disease, non-alcoholic fatty liver disease and autoimmune hepatitis) are nevertheless well-established risk factors for COVID-19.

In one study in Italy, Pavarin et al. (2022) confirmed the hypothesis that people with Substance or Alcohol Use Disorders (SUDs/AUDs) have higher risk of symptomatic COVID-19 infection that requires hospitalization compared to the general population. Furthermore, they found higher mortality rates during hospitalization for COVID-19 in patients with AUDs or SUDs than the general population. In the multivariate analysis, **the RR adjusted for sex and age were significantly higher for total AUD patients (RR=1.7, 95% CI: 1.29–2.24 for hospitalization and RR=2.25, 95% CI: 1.16–4.37 for mortality of 50+y)** compared to the resident population. Among the subjects hospitalized for COVID-19, there were no deaths among females and patients aged between 30 and 49 years.

More study are needed to confirm this risk in a larger scale for COVID-19. To our knowledge, there are as yet no VE data published specific to people who drink alcohol excessively and for the Omicron period. Nevertheless, vaccination should reduce the risk for these people too.

B) Pregnancy (without other comorbidities/high-risk pregnancy)

Pregnancy is a known risk factor for severe COVID-19 disease. However, for women who have previously received primary COVID-19 vaccination and are otherwise healthy, absolute risks remain relatively low. These women MAY OPT for COVID-19 vaccination on an individual basis. This decision should involve a conversation with a healthcare provider, taking into account priorities and risk factors for all vaccinations recommended by NITAG (SHC 8754, 2020; SHC 9760, 2023; SHC 9831, 2024).

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At present, in the context of circulating variants, **routine vaccination of healthy children, adolescents and adults under 64 (not included in groups described above) is not recommended by the SHC.** If they wish (for whatever reason, including travel), they can receive the booster (VE and safety data are favorable), but this is based solely on an individual decision and not on a strong scientific recommendation as to the usefulness of this vaccination for them.

3 Vaccination schedules for VOC-adapted COVID-19 vaccines

The VOC-adapted COVID-19 vaccines considered in this report are the mRNA-adapted vaccines Comirnaty®, Spikevax® and the recombinant, adjuvanted vaccine Nuvaxovid®. If not specified in the report, the Council always refers to the EMA and the Belgian FAMHP recommendations regarding the dosage, the schedule and the route of administration of these vaccines.

4 Timing of Autumn / Winter season 2025 – 2026 COVID-19 vaccination

The timing of COVID-19 booster administration should be guided by epidemiological, logistical considerations and population acceptability, in order to achieve **the highest possible vaccine coverage in at-risk groups for both COVID-19, Influenza, pneumococcal and RSV for the 65+ years old and other target groups**.

It is impossible to predict when and how COVID-19 will emerge in the next season, or to estimate its severity and virulence or the impact on Influenza-like Illness (ILI) and others Severe Acute Respiratory Infections (SARI). Based on previous years,

- The COVID-19 virus circulates weakly throughout the year (including summer), often peaking in **early autumn and late winter**.

- The flu season, on the other hand, appears to be more limited in time (6 to 12 weeks), with **a later peak in incidence than for COVID-19**.

- In Belgium and the northern hemisphere in general, RSV infection occurs as a seasonal epidemic between **early October and late March**, with winter peaks in mid-December. Due to the currently 3y-efficacy of the RSV vaccination, the timing of vaccination is less important for this disease.

- Pneumococcal infections are most common during the winter months in the northern hemisphere, including Belgium but can occur all during the year. This means that the most critical period for these infections is generally between **November and March** but, due to the long-term efficacy of the pneumococcal vaccination, the timing of vaccination is less important for this disease.

As recommended by the World Health Organization (WHO) and the European Centre for Disease Prevention and Control ECDC, this year, the SHC recommends that vaccination against COVID-19 and seasonal influenza **should preferably be offered jointly in October** (WHO, 2022; ECDC, 2023).

If COVID-19 and Influenza vaccinations are deferred for personal or logistical reasons, the risk groups recommended for COVID-19 should be vaccinated in the period September to October, and from mid-October for Influenza.

It is up to the competent authorities to determine the start of the campaign to achieve this goal, keeping in mind that the further away the vaccination is from the onset of the wave of infections, the more likely it is that the protection provided by the vaccines will be diminished, especially with regard to symptomatic infections and transmission risks. The longer the interval towards the booster, the more the waning is pronounced.

To simplify the system and to obtain the highest possible level of protection and ensure consistency with previous recommendations, 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. An infection before or after completion of COVID-19 vaccination has a booster effect and the greatest levels of protection against circulating (and probably future?) variant were provided by hybrid immunity.

5 Minimum interval between booster doses

As previously recommended (SHC 9683, 2021), the SHC recommends an interval **of minimum 6 months** for the administration of an additional VOC-adapted COVID-19 vaccine booster dose.

6 Additional spring 2025 COVID booster for 85 years old and over and IC patients

In light of the data presented by Sciensano on 26 January 2023 for people over 85 years of age and immunocompromised people based on their vaccination status, the limited scientific data still available on modified BA4/5 vaccines (Link-Gelles et al., 2022; Tenforde et al. 2022; Surie et al., 2022; Zou et al., 2022; Muik et al., 2022), the ECDC recommendations and mathematical modelling released on 05/04/2023, Strategic Advisory Group of Experts on Immunization (SAGE - OMS) and EU NITAG meetings, and the opinion of NITAG experts, the SHC conclude that:

Adults aged of 85 years and older and some immunocompromised (IC - due to disease or treatment) people/patients **can receive an additional booster upon individual request** after an individual benefit/risk analysis with the physician (Dhanasekaran et al., 2024; Shoham et al., 2025; Roper et al., 2025; ACIP-CDC, 2025; Zhang et al., 2025), if they are clearly informed that:

- it is currently not systematically recommended by NITAG;
- not clearly supported by the Belgian epidemiological and VE data;
- it is an off-label administration;
- should be administered at least 6 months after the last winter booster injection.

7 Homologus vs heterologous vaccine regimens strategy

In view of the literature review and conclusions, the SHC is of the opinion that COVID-19 homologous (same vaccines) or heterologous (vaccines from different platforms) vaccine regimens with vaccines adapted to the circulating variant are scientifically sound, interchangeable and therefore usable-acceptable in Belgium in terms of VE and safety.

Since the main objective is to have **a winter vaccination campaign with the highest possible coverage of all at-risk groups for the main winter respiratory diseases** (Influenza, COVID-19, RSV, Pneumococcus), the choice of COVID-19 vaccines to be offered

is left to the discretion of the Belgian authorities, depending on availability and Belgian and European logistical constraints for the purchase and distribution of the adapted COVID-19 vaccines.

8 Safety

Any person that experiences possible adverse effects after vaccination should consult a healthcare provider. Patients and healthcare providers **are encouraged to declare these effects to the authorities in charge of post-marketing surveillance**, as is always recommended for any concerns about vaccination. Reporting of adverse reactions can be done directly to www.notifieruneffetindesirable.be or www.eenbijwerkingmelden.be.

9 Vaccine availability (outside the Autumn / Winter season)

Whether it's for pregnant women, immunocompromised patients, elderly and frail people whose vaccination schedule needs to be adapted to their specific status, illnesses or treatments, for people wishing to have a second booster vaccination a year, or in the event of clusters occurring at a time of year other than the autumn/winter season, the Council recommends that the Belgian authorities make **COVID-19 vaccines available all year round, with particular attention to the winter season**.

10 VE for 2024-2025 season

CDC estimated interim effectiveness of 2024-2025 COVID-19 vaccines in adults during September 2024-January 2025. VE against COVID-19-associated emergency department visits in adults ≥18y was 33% (95% CI = 28%-38%) during the first 7-119 days after vaccination. Among immunocompetent adults aged ≥65 years from two CDC networks, VE estimates against COVID-19-associated hospitalization were 45% (95% CI = 36%-53%) and 46% (95% CI = 26%-60%) during the first 7-119 days after vaccination. Among adults aged ≥65 years with immunocompromising conditions in one network, VE was 40% (95% CI = 21%-54%) during the first 7-119 days after vaccination. These findings demonstrate that vaccination with a 2024-2025 COVID-19 vaccine dose provides additional protection against COVID-19-associated ED/UC encounters and hospitalizations compared with not receiving a 2024-2025 dose (Link-Gelles et al., 2025).

In the EU, although currently only VE results from primary care are available, in a multicenter, test-negative design study at primary care level within the VEBIS network, VE against medically-attended SARS-CoV-2 infection was 67% (95% CI 33-86) among older adults ≥ 60 or ≥ 65 years according to country-specific recommendations (Laniece Delaunay et al., 2025).

In Belgium, preliminary estimates for VE against hospitalization are available through the network of hospitals participating in the surveillance of SARI. Using a test-negative design, analysis of 2,350 hospitalizations (of which 144 caused by COVID-19) occurring between end of September 2024 and early April 2025 yielded an overall VE against hospitalization of 51.4% (95% 19.3-70.7). Due to the overall limited number of COVID-19 hospitalizations during the past winter season, further analyses stratified by time after vaccination or age are not informative (Sciensano, unpublished data). More specific data for Belgium on VE on previous seasons are available in multiple reports of Sciensano (Surveillance van acute luchtweginfecties: epidemiologisch rapport seizoenen 2022-2023 en 2023-2024 | sciensano.be).

III METHODOLOGY

***Remarks**: the evolution of knowledge and the scientific background behind these conclusions and recommendations can be consulted in our various reports til the beginning of the COVID-19 pandemic and will therefore no longer be the subject of a detailed chapter in this annual revision.*

1 Expertise and potential risk of conflicts of interest

After analysing the request, the Board and the Co-Chairs of the area vaccination identified the necessary fields of expertise. The request was then entrusted to the experts at NITAG group which included experts in vaccinology, geriatrics, general medicine, paediatrics, microbiology, infectiology, epidemiology, etc. 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.

2 General methodology

This advisory report is based on a review of the scientific literature published in both scientific journals and reports from national and international organisations competent in this field (peer-reviewed), as well as on the opinion of the experts. This scientific advisory report aims to provide an overview of the latest vaccination strategy for COVID-19 proposed by the NITAG and SHC. This report is based on previous advisory report of the SHC, ECDC recommendations and mathematical modelling, literature review (mainly systematic reviews and meta-analysis), other NITAG reports (cf. references section) and the latest epidemiological data and modelling available.

The reference publications with associated scientific evidence used to draw up the risk group list are:

SHC – Superior Health Council. Recommendations for SARS-CoV-2 vaccination of pregnant women, women who are pregnant, intend to become pregnant or are breastfeeding using a messenger RNA vaccine. Brussels: SHC; 21/05/2021. Report 9622. https://www.health.belgium.be/fr/avis-9622-vaccination-contre-la-covid-19-chez-la-femme-enceinte

SHC – Superior Health Council. Recommendations for prioritisation of subgroups of patients under 65 years of age for vaccination against SARS-CoV-2 (Phase Ib). Brussels: SHC; 05/02/2021. Report 9618. https://www.health.belgium.be/fr/avis-9618-la-priorisation-des-groupes-risque-pour-la-vaccination-contre-le-sars-cov-2-phase-ib

SHC – Superior Health Council. Booster vaccination against COVID-19 for immunocompromised patients. Brussels: SHC; 03/03/2022. Report 9691. https://www.health.belgium.be/en/report-9691-booster-vaccination-immunocompromised-patients

SHC - Superior Health Council. Vaccination against COVID-19 with mRNA vaccines for children from 6 months of age in Belgium. Brussels: SHC; 2022. Report 9722. https://www.health.belgium.be/en/report-9722-vaccination-against-covid-19-infants-and-children

CDC - Centers for Disease Control and Prevention. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals (systematic review) - CDC, 06/02/2025.

ECDC - European Centre for Disease Prevention and Control. Interim public health considerations for COVID-19 vaccination roll-out during 2023. 5 April 2023. Stockholm: ECDC; 2023. https://www.ecdc.europa.eu/en/publications-data/interim-public-health-considerations-covid-19-vaccination-roll-out-during-2023

3 Scoping and specific questions and research method for 2025

1) According to the literature review, no specific question is specifically addressed in the context of this revision 2024-2025.

2) An updated literature search was conducted on Pubmed (2024-2025) using the following terms : "COVID-19"[Mesh]; "Vaccination"[Mesh]; "Review" [Publication Type]. 348 new abstracts published since the last version of this advisory report have been analyzed, incorporated when necessary and completed by NITAG experts propositions.

4 Validation process

One NITAG meeting (June 2025) will result in consensus on conclusions and recommendations, with experts contributing specific references and comments via email. Once the advisory report was endorsed by the NITAG, it was ultimately validated by the Board and by mail by the NITAG on 02 Juli 2025.

Specific chapters, **containing only general information**, has been partially written with the assistance of artificial intelligence (ChatGPT 4o/o3 or Gemini 2.5 Flask Deep Research) and validated by NITAG members.

5 Keywords

Keywords	**Sleutelwoorden**	**Mots clés**	**Schlüsselwörter**
Prevention	Preventie	Prévention	Verhütung
Booster	Booster	Rappel (dose)	Auffrischimpfung
COVID-19	COVID-19	COVID-19	COVID-19
Pregnancy	Zwangerschap	Grossesse	Schwangerschaft
Omicron	Omicron	Omicron	Omicron
Drug-Related Side Effects and Adverse Reactions	Geneesmiddel-gerelateerde bijwerkingen en nevenreacties	Effets secondaires et réactions indésirables liés aux médicaments	Medikamentenbedingte Nebenwirkungen und unerwünschte Wirkungen
Vaccination	Vaccinatie	Vaccination	Impfung

6 List of abbreviations used

AIDS	Acquired immunodeficiency syndrome
ACE2	Angiotensin-Converting Enzyme 2
ARDS	Acute Respiratory Distress Syndrome
AUD	Alcohol Use Disorders
BeRS	Belgian Respiratory Society - BE
BMI	Body Mass Index
CDC	Centers for Disease Control and Prevention - US
CDK	Chronic Kidney Disease
CGD	Chronic Granulomatous Disease
CI	Confidence Interval
COPD	Chronic Obstructive Pulmonary Disease
COVID-19	Coronavirus disease 2019
ECDC	European Centre for Disease Prevention and Control - EU
EMA	European Medicines Agency - EU
EPAR	European Public Assessment Report
ETF	Emergency Task Force (EMA) - EU
FAMHP	Federal Agency for Medicines and Health Products - BE
FDA	Food and Drug Administration - US
FMF	Familial Mediterranean Fever
GINA	Global Initiative for Asthma - INT
HIV	Human Immunodeficiency Virus
HLH	Lymphohistiocytosis
HPV	Human Papillomavirus
IC	Immunocompromise people (due to disease or treatment)
ICU	Intensive Care Unit
ILI	Influenza-Like Illness (flu-like symptoms: fever, cough and/or shortness of breath and general malaise. These symptoms can be caused by many different germs, not just the flu virus.
KRINKO	*Kommission für Krankenhaushygiene und Infektionsprävention* - DE
LTCF	Long Term Care Facilities
MIS-C	Multisystem inflammatory syndrome in children
mRNA	Messenger ribonucleic acid
NCHS	National Center for Health Statistics - US
NICU	Neonatal Intensive Care Unit
NITAG	National Immunization Technical Advisory Group - BE
NNV	Number Needed to Vaccinate
NPI	Non-Pharmaceutical Intervention
NVSS	National Vital Statistics System - US at NCHS
OR	Odds Ratio
PCR	Polymerase Chain Reaction
PCP	Pregnancy Care Provider
PID	Primary immunodeficiencies
RR	Risk Ratio
RIVM	Rijksinstituut voor Volksgezondheid en Milieu - NL
RMG	Risk Management Group - BE
RSV	Respiratory Syncytial Virus
SAE	Serious Adverse Events
SAGE	Strategic Advisory Group of Experts on Immunization – INT WHO
SARI	Severe Acute Respiratory Infection (hospitalization of at least 24 hours for severe complaints of acute respiratory infection (fever, cough and/or shortness of breath)
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SHC	Superior Health Council - BE
SIZ	Belgian Society of Intensive Care Physicians - BE
SUCRA	Surface Under the Cumulative Ranking Curve
SUD	Substance Use Disorders
USA	United States of America
VE	Vaccine Effectiveness or Efficacy
VITT	Vaccine-Induced Thrombotic Thrombocytopenia
VOC	Variants Of Concern
VOI	Variants Of Interest
WHO	World Health Organization - INT

IV ELABORATION

1 COVID-19 disease and risk factors

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COVID-19 is caused by the SARS-CoV-2 virus, which belongs to the coronavirus family. Coronaviruses are enveloped, single-stranded RNA viruses that primarily infect the respiratory system. SARS-CoV-2 shares similarities with other coronaviruses such as SARS-CoV and MERS-CoV but differs in its transmissibility and spread. The virus primarily targets the angiotensin-converting enzyme 2 (ACE2) receptors found in various tissues, including the lungs, heart, and gastrointestinal system.

Since the pandemic's onset, SARS-CoV-2 has undergone significant genetic evolution, driven by mutations in its genome, particularly in the spike (S) protein, which facilitates viral entry into host cells. These mutations have led to the emergence of several variants, classified by organizations like WHO as VOCs or Variants of Interest (VOIs). The SARS-CoV-2 virus has undergone significant evolution since its initial identification in December 2019 with the Wuhan-Hu-1 strain, commonly referred to as the wild type. As the pandemic progressed, the virus accumulated mutations, leading to the emergence of several variants that altered its transmissibility, virulence, and immune evasion capabilities. Early in the pandemic, the D614G mutation in the spike protein appeared, becoming the dominant form of the virus by mid-2020. This mutation increased the virus’s infectivity and laid the groundwork for the variants that followed. One of the first major variants to emerge was Alpha (B.1.1.7), identified in the UK in late 2020. Alpha exhibited significantly enhanced transmissibility and was associated with a higher risk of severe disease, making it a concerning development at the time. Shortly after, Beta (B.1.351) was detected in South Africa, distinguished by multiple spike protein mutations that allowed it to partially escape neutralizing antibodies. This feature made it more resistant to both natural immunity and vaccines, posing a challenge to public health efforts. Around the same time, Gamma (P.1) was identified in Brazil. Gamma shared many mutations with Beta, including similar resistance to antibodies, which further complicated efforts to contain the spread. The next major variant, Delta (B.1.617.2), was first detected in India in late 2020 and quickly became the dominant strain globally by mid-2021. Delta was far more transmissible than previous variants and was associated with more severe disease, leading to waves of infections and overwhelming healthcare systems in many regions. In late 2021, Omicron (B.1.1.529) was first identified in South Africa, representing a significant evolutionary leap. Omicron contained a large number of mutations in its spike protein, resulting in even higher transmissibility and substantial immune evasion. Despite these traits, Omicron was associated with milder disease outcomes in many cases, though its currently circulating sub lineages.

SARS-CoV-2 primarily enters the body via the respiratory system, where it binds to ACE2 receptors on the surface of epithelial cells, particularly in the lungs. Once inside the cell, the virus hijacks the host’s machinery to replicate, leading to widespread cell damage and triggering an immune response.

The pathophysiology of COVID-19 could be divided into three stages:

- **Early infection (mild stage)**: the virus replicates in the upper respiratory tract, causing mild symptoms like fever, cough, and fatigue. Some individuals remain asymptomatic at this stage.
- **Pulmonary phase (moderate to severe stage)**: as the virus migrates to the lower respiratory tract, it induces inflammation in the lungs, leading to viral pneumonia. This phase is characterized by cough, shortness of breath, and hypoxia (low oxygen levels).
- **Hyperinflammatory phase (severe to critical stage)**: In some cases, an excessive immune response occurs, leading to a cytokine storm. This hyperinflammation can result in acute respiratory distress syndrome (ARDS), multi-organ failure, and death. The vascular endothelium is also affected, contributing to clot formation (thrombosis) and other cardiovascular complications.

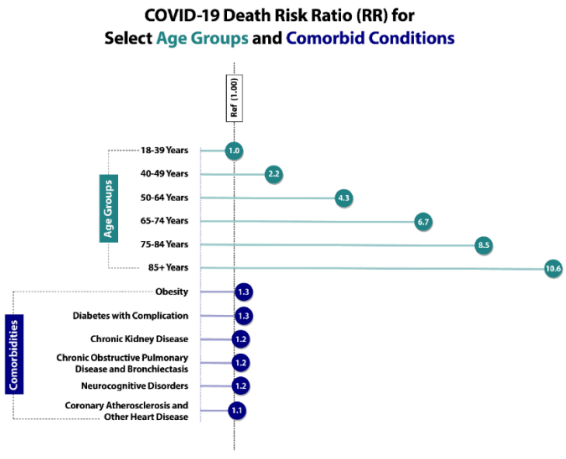
COVID-19 presents with a wide range of symptoms, varying in severity. The main symptoms include: fever, cough (usually dry), fatigue, shortness of breath or difficulty breathing, loss of taste or smell, muscle or joint pain, sore throat, headache, chills, nausea or vomiting, diarrhea. In severe cases, symptoms progress to pneumonia, respiratory failure, and multi-organ dysfunction.

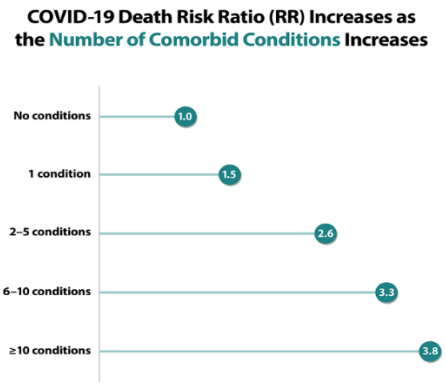
Age remains the strongest risk factor for severe COVID-19 outcomes, with risk of severe outcomes increasing markedly with increasing age. Based on data from the National Vital Statistics System (NVSS) at National Center for Health Statistics (NCHS), compared with ages 18–29 years, the risk of death is 25 times higher in those ages 50–64 years, 60 times higher in those ages 65–74 years, 140 times higher in those ages 75–84 years, and 340 times higher in those ages 85+ years.

Certain specific populations are also more vulnerable to severe COVID-19 disease, including:

- **People with underlying health conditions**: these include cardiovascular diseases, diabetes, chronic respiratory diseases, obesity, cancer, and immune-compromised states (SHC 9618, 2021).
- **People with immunosuppressive conditions**: this includes individuals with active HIV/AIDS, those on immunosuppressive therapies, and organ transplant recipients (SHC 9691, 2022).
- **Pregnant women**: there is evidence suggesting an increased risk of severe disease and pregnancy complications (SHC 9622, 2021).
- **Unvaccinated individuals**: those without prior vaccination or immunity, either through previous infection or vaccination, remain at higher risk of severe disease, particularly with emerging variants.

https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html





In Belgium, for people with underlying conditions, vaccination against COVID-19 offers protection against hospitalization and ICU admission. For example, during the period of Omicron variant dominance, the initial protection of a first booster dose in people aged 65 and over, with at least one underlying condition, was estimated at 68.2% against hospitalization and 73.2% against ICU admission. These estimates showed lower vaccine protection efficacy against both hospitalization and ICU admission in people with underlying conditions compared to those without, irrespective of age. During the period of Omicron dominance and against hospitalization, the initial protection of a first booster dose was estimated at 68.2% for people aged 65 and over with underlying conditions versus 88.3% for those without conditions, that of the second booster at 30.0% versus 64.0%, respectively. For the same period and against ICU admission, the initial protection of a first booster dose was estimated at 73.2% for people aged 65 and over with underlying conditions versus 91.4% for those without conditions (Stouten et al., 2023 - Sciensano).

2 Transmission – NPI - Ventilation

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For more general and validated scientific information : https://www.health.belgium.be/fr/covid-19

COVID-19, caused by the SARS-CoV-2 virus, spreads primarily through several modes of transmission:

Respiratory Droplets: The most common method of transmission is via respiratory droplets expelled when an infected person coughs, sneezes, talks, or breathes. These droplets can be inhaled by others nearby, typically within a distance of about 1-2 meters.

Aerosols: In some settings, especially in poorly ventilated indoor spaces, the virus can remain suspended in the air as smaller aerosol particles. These aerosols can travel farther than respiratory droplets and linger in the air for longer periods, increasing the potential for airborne transmission, especially over extended exposure.

Fomites (Surface Contact): Although less common, transmission can occur by touching surfaces or objects contaminated with the virus and then touching the face, mouth, nose, or eyes. However, this mode of transmission is now considered secondary to airborne transmission.

Asymptomatic Transmission: Individuals who are infected but do not show symptoms (asymptomatic carriers) or those who are pre-symptomatic can still transmit the virus, complicating efforts to control its spread.

Non-pharmacological interventions (NPIs) have been critical in limiting the spread of COVID-19, especially before vaccines became widely available. These measures remain important, particularly when viral transmission is high or in settings with vulnerable populations. Key NPIs include:

Physical Distancing: keeping a distance of at least 1-2 meters from others reduces the likelihood of inhaling respiratory droplets containing the virus. This measure is especially effective in crowded or indoor settings.

Face Masks: wearing face masks, particularly well-fitting surgical masks (or respirators - N95, FFP2), significantly reduces the transmission of both droplets and aerosols. Masks are especially important in crowded indoor spaces or where physical distancing is not possible.

Hand Hygiene: regular handwashing with soap and water for at least 20 seconds or using alcohol-based hand sanitizers (with at least 60% alcohol) helps reduce the risk of transmission via contaminated surfaces.

Ventilation: improving indoor ventilation by increasing the flow of outdoor air into buildings or using air filtration systems helps dilute and remove virus particles in the air, reducing the risk of aerosol transmission. Ventilation measures are particularly important in schools, workplaces, and public spaces (SHC 9616, 2020 et 2021).

3 Epidemiology

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For updated and validated scientific numbers on epidemiology, please only refer to:

https://data.who.int/dashboards/covid19/cases (World)
https://www.ecdc.europa.eu/en/covid-19/situation-updates (Europe)

For updated and validated scientific numbers on epidemiology, please only refer to:

https://covid-19.sciensano.be/fr/covid-19-situation-epidemiologique (Belgium)
https://lookerstudio.google.com/embed/reporting/c14a5cfc-cab7-4812-848c-0369173148ab/page/ZwmOB (Belgium)

Evolution of key indicators

Since late 2019, the COVID-19 pandemic has profoundly impacted global public health. The continuous emergence of SARS-CoV-2 variants, each with distinct characteristics, makes ongoing surveillance and adaptation of public health strategies crucial. Genomic surveillance is essential to rapidly detect new variants, assess their risk (transmissibility, severity, immune evasion), and guide public health responses (vaccine development and treatments).

The global epidemiology of COVID-19 shows complex dynamics. Since Omicron's arrival and widespread vaccination, COVID-19-related mortality has generally decreased worldwide. However, the number of infections continues to fluctuate, often seasonally. This divergence highlights that global averages can mask significant regional dynamics, influenced by local variants, vaccination coverage, and waning immunity.

The burden on healthcare systems has also decreased, with fewer ICU admissions despite case increases. This is likely due to widespread immunity (vaccination and prior infections) and potentially a lower intrinsic severity of currently dominant variants. While hospitalizations persist, especially in winter, fewer patients require critical care.

Annual excess mortality is a crucial indicator to assess the pandemic's overall impact, including both direct and indirect deaths. Resources like Our World in Data and Sciensano (for Belgium - https://www.sciensano.be/fr/sujets-sante/mortalite/role) track this indicator.

Alpha, Beta, Gamma, and Delta variants preceded Omicron, which has dominated the global landscape since late 2021 with its many sub-lineages (e.g., JN.1, LP.8.1, XEC, KP.3, NB.1.8.1). The shift from more severe variants (Delta) to Omicron, which is more transmissible and immune-evasive but potentially less severe, marks a fundamental change. The rapid succession of Omicron sub-lineages indicates significant selective pressure favoring viral fitness, necessitating vaccine updates and constant genomic surveillance.

Table: Timeline of SARS-CoV-2 variants (VOC, VOI, VUM) – key features

Variant Name	Classification OMS	Date de Désignation/Évaluation Initiale des Risques	Caractéristiques Génétiques Clés	Impact Épidémiologique/Phénotypique Primaire	Période de Dominance (approximative)
Alpha	VOC (précédemment)	Décembre 2020 (UK)	N501Y, P681H, E484K (sous-lignages)	Transmissibilité accrue, affinité de liaison ACE2 améliorée, évasion immunitaire (E484K)	Fin 2020 Mi-2021
Beta	VOC (précédemment)	Mai 2020 (Afrique du Sud)	N501Y, E484K, K417N, L18F	Évasion immunitaire, transmissibilité améliorée	Mi-2021
Gamma	VOC (précédemment)	Janvier 2021 (Brésil)	K417N, E484K, N501Y, L18F, P681H	Transmissibilité accrue, évasion immunitaire	Mi-2021
Delta	VOC (précédemment)	Décembre 2020 (Inde)	(Spécifique à la lignée)	Transmissibilité et sévérité accrues	Mi-2021 Fin 2021
Omicron	VOC	Novembre 2021 (Afrique du Sud)	>50 mutations (26-32 dans la protéine Spike)	Transmissibilité très élevée, évasion immunitaire significative, sévérité potentiellement réduite	Fin 2021 Présent
XBB	Sous-lignage d'Omicron	Fin 2022	Recombinant de BA.2 descendants (BM.1.1.1 et BJ.1)	Évasion immunitaire, transmissibilité	Fin 2022 Mi-2023
JN.1	VOI (depuis Déc. 2023)	25-08-2023 (échantillon) / 18-12-2023 (désignation)	BA.2.86 + S:L455S	Transmissibilité élevée, évasion immunitaire	Fin 2023 Début 2024
LP.8.1	VUM	01-07-2024 (échantillon) / 24-01-2025 (désignation)	JN.1+ S:S31-, S:F186L, S:R190S, S:R346T, S:V445R, S:F456L, S:Q493E, S:K1086R, S:V1104L	Transmissibilité, évasion immunitaire, moins sévère que les souches précédentes	Début 2025
XEC	VUM	26-06-2024 (échantillon) / 24-09-2024 (désignation)	JN.1 + S:T22N, S:F59S, S:F456L, S:Q493E, S:V1104L	Transmissibilité, évasion immunitaire, moins sévère que les souches précédentes	Début 2025
KP.3	VUM	11-02-2024 (échantillon) / 03-05-2024 (désignation)	JN.1 + S:F456L, S:Q493E, S:V1104L	Transmissibilité, évasion immunitaire	Début 2025
NB.1.8.1	VUM	22-01-2025 (échantillon) / 23-05-2025 (désignation)	JN.1 + S:T22N, S:F59S, S:G184S,S:A435S, S:F456L, S:T478I, S:Q493E	Transmissibilité, légère évasion immunitaire, pas d'augmentation de la sévérité	Mi-2025

In the United States, the CDC genomically monitors SARS-CoV-2. From May 2023 to September 2024, Omicron XBB and JN.1 lineages predominated, leading to infection waves. By early 2025, LP.8.1 and XEC became the main strains, accounting for 73% of new COVID-19 cases in March. The CDC's COVID-19 Hospitalization Surveillance Network (COVID-NET) monitors laboratory-confirmed COVID-19 hospitalizations and provides data on clinical characteristics, including the need for mechanical ventilation. Initial data from 2020-2021, during the Delta variant's dominance, showed a substantial proportion of hospitalized patients requiring oxygen, intensive care, and mechanical ventilation. A small but significant number also needed ECMO (Extracorporeal Membrane Oxygenation), included among male and/or obese children and adolescents in the US, a trend less observed in Europe during the same period. More recent data from early 2025 suggests that current variants are "less severe" leading to fewer emergency department visits. This reduction in severity is attributed to widespread pre-existing immunity within the population.

In Europe, the ECDC tracks five SARS-CoV-2 variants, including NB.1.8.1. Slow increases in epidemiological indicators are observed in June 2025, but with no significant impact on healthcare or deaths. NB.1.8.1 is expected to increase due to waning immunity and slight immune evasion, but without increased severity. We also observed the same evolution on key indicators.

European data on COVID-19 hospital burden, particularly ECMO use, showed high mortality during pre-Omicron waves. However, the case fatality rate in most of Europe decreased by at least 90% between early March and early May 2020 and remains low in June 2025 despite new variant circulation. This reinforces the idea that COVID-19 is evolving into an endemic respiratory virus, where case fluctuations no longer translate into overwhelming mortality, thanks to hybrid immunity and effective vaccination strategies.

Vaccine Effectiveness (VE) and Waning Immunity

Waning immunity differs between protection against infection and against severe outcomes. While vaccine effectiveness against infection can decline quickly, protection against hospitalization and death remains more durable. Vaccines showed high initial effectiveness against early variants (Alpha, Delta, Beta, Gamma). However, Omicron's emergence, with over 50 mutations, reduced grouped VE against infection to 55.9%, but booster doses significantly improved VE against severe forms (80.8%).

CDC estimated interim effectiveness of 2024-2025 COVID-19 vaccines in adults during September 2024-January 2025. VE against COVID-19-associated emergency department visits in adults ≥18y was 33% (95% CI = 28%-38%) during the first 7-119 days after vaccination. Among immunocompetent adults aged ≥65 years from two CDC networks, VE estimates against COVID-19-associated hospitalization were 45% (95% CI = 36%-53%) and 46% (95% CI = 26%-60%) during the first 7-119 days after vaccination. Among adults aged ≥65 years with immunocompromising conditions in one network, VE was 40% (95% CI = 21%-54%) during the first 7-119 days after vaccination. These findings demonstrate that vaccination with a 2024-2025 COVID-19 vaccine dose provides additional protection against COVID-19-associated ED/UC encounters and hospitalizations compared with not receiving a 2024-2025 dose (Link-Gelles et al., 2025).

In the EU, although currently only VE results from primary care are available, in a multicenter, test-negative design study at primary care level within the VEBIS network, VE against medically-attended SARS-CoV-2 infection was 67% (95% CI 33-86) among older adults ≥ 60 or ≥ 65 years according to country-specific recommendations (Laniece Delaunay et al., 2025).

In Belgium, preliminary estimates for VE against hospitalization are available through the network of hospitals participating in the surveillance of SARI. Using a test-negative design, analysis of 2,350 hospitalizations (of which 144 caused by COVID-19) occurring between end of September 2024 and early April 2025 yielded an overall VE against hospitalization of 51.4% (95% 19.3-70.7). Due to the overall limited number of COVID-19 hospitalizations during the past winter season, further analyses stratified by time after vaccination or age are not informative (Sciensano, unpublished data). More specific data for VE in Belgium are available in multiple reports of Sciensano (Surveillance van acute luchtweginfecties: epidemiologisch rapport seizoenen 2022-2023 en 2023-2024 | sciensano.be).

In conclusion, COVID-19 has transitioned from an acute crisis to a more endemic phase, dominated by highly transmissible Omicron sub-lineages that generally cause less severe illness in immunized populations. While global reported cases and deaths have decreased, regional variations and increases persist, driven by waning immunity and new variants. Vaccine effectiveness, especially against severe forms, remains robust with updated formulations and booster doses, highlighting vaccination's essential role in mitigating disease burden. The virus no longer causes the same level of severe illness as it did initially, largely thanks to widespread immunity and potentially attenuated variants. Public health strategies must adapt, shifting from general emergency measures to targeted interventions, focusing on protecting vulnerable populations and promoting routine vaccination.

4 Compared Vaccine Effectiveness (VE) and Safety profiles of various COVID-19 vaccine platforms approved by the EMA during Omicron period

Across all platforms, the immunity provided by COVID-19 vaccines diminishes over time, necessitating periodic updates to the vaccine formulations to address new variants. This is similar to the approach used for annual influenza vaccines. **Despite the waning of protection against mild to moderate infection, the vaccines remain crucial in preventing severe disease outcomes**. Regular boosters or updated vaccines are recommended to maintain a higher level of immunity, **especially for vulnerable populations** (Nasiadka et al., 2023 – Sciensano ; Stouten et al., 2023 – Sciensano).

Published information on the evaluation of the efficacy/effectiveness and safety of the CoronaVac (whole inactivated virus COVID-19 vaccine developed by Sinovac Biotech) is abundant. However, there are differences in terms of vaccine application schedules, population definition, outcomes evaluated, follow-up times, and safety assessment, as well as non-standardization in the reporting of results, which may hinder the generalizability of the findings. **It is important to generate meetings and consensus strategies for the methods and reporting of this type of studies, which will allow to reduce the heterogeneity in their presentation and a better understanding of the effect of these vaccines** (Alzate-Ángel et al., 2024). The mRNA vaccines, adenovirus vector vaccines, subunit vaccines, and inactivated vaccines were found **to be all effective**. mRNA vaccines, adenovirus vector vaccines and subunit vaccines were associated with more local adverse events and systemic events when compared with inactivated vaccines (Jiesisibieke et al., 2023).

Real-world vaccine effectiveness, research by Kherabi and collaborators (2022), provided real-world data on the effectiveness of COVID-19 vaccines against the Omicron variant. The efficacy of vaccines against COVID-19 has now been well established in phase III clinical trials. However, clinical studies based on real-world data remain critical to assess VE, especially in specific populations and against VOC. This review presents the principles and methods of VE studies and the main available results on VE of COVID-19 vaccines at the time of Omicron circulation. **The results of phase III clinical trials have been globally confirmed by VE in real-life studies, including in the elderly**. Emergence of VOC **Omicron emphasized the importance of booster doses** to maintain a high level of protection against severe forms. Our understanding of the need for booster(s) and duration of immunity remains incomplete, particularly for specific subpopulations. **The necessity for adapted vaccines is also not fully clear**. These areas represent significant gaps in our current knowledge base. This study noted that while mRNA vaccines continued to show good effectiveness, the emergence of Omicron necessitated additional booster doses to maintain high levels of protection (Kherabi et al., 2022).

Real-world data from Taiwan on VE against the Omicron variant showed that **mRNA vaccines, when used heterologous vaccine schedule, provided substantial protection against infection, severe illness, and death**. The mix-and-match strategy, involving various combinations of mRNA, viral vector, and protein-based vaccines, proved effective, thus underscoring the flexibility and robustness of mRNA vaccines in broader immunization strategies. The findings indicated that **protein subunit vaccines provide similar protection against SARS-CoV-2-associated hospitalization as mRNA vaccines and can inform mix-and-match vaccine selection in other countries** (Lee et al., 2024). Other studies highlighted the advantages of heterologous vaccine regimens (combining different types of vaccines) over homologous regimens (using the same vaccine type). It is noted that schedules combining adenovirus-vectored vaccines with mRNA vaccines induced stronger immune responses and higher effectiveness against COVID-19 compared to using adenovirus-vectored vaccines alone. This suggests that **while mRNA vaccines are highly effective, their combination with other vaccine types can enhance immunogenicity and effectiveness** (Steenackers et al., 2024; Jin et al., 2022; Piano et al., 2025).

A network meta-analysis published in 2022 examined **the efficacy and safety of various COVID-19 vaccines**, including mRNA, viral vector, protein subunit, and inactivated virus vaccines. Over a dozen vaccines are in or have completed phase III trials at an unprecedented speed since the WHO declared COVID-19 a pandemic. In this review, the authors aimed to compare and rank these vaccines indirectly in terms of efficacy and safety using a network meta-analysis. **None of vaccines had a higher incidence of Serious Adverse Events (SAE) than the placebo**. Inactivated virus vaccines might be the safest, with a surface under the cumulative ranking curve (SUCRA) value of 0.16. BIV1-CovIran showed the highest safety index (SUCRA value: 0.13), followed by BBV152, Soberana, Gam-COVID-Vac, and ZF2001. **There were no significant differences among the various types of vaccines regarding the efficacy in preventing symptomatic SARS-CoV-2 infection, although there was a trend toward higher efficacy of the mRNA vaccines** (SUCRA value: 0.09). BNT162b2 showed the highest efficacy (SUCRA value: 0.02) among the individual vaccines, followed by mRNA-1273, Abdala, Gam-COVID-Vac, and NVX-CoV2373. BNT162b2 had the highest efficacy (SUCRA value: 0.08) in the elderly population, whereas CVnCoV, CoVLP + AS03, and CoronaVac were not significantly different from the placebo. Conclusions: **None of the different types of vaccines were significantly superior in terms of efficacy, while mRNA vaccines were significantly inferior in safety to other types**. BNT162b2 had the highest efficacy in preventing symptomatic SARS-CoV-2 infection in adults and the elderly, whereas BIV1-CovIran had the lowest incidence of SAEs in adults (Wu et al., 2024).

In general, like for non-updated COVID-19 vaccines, scientific evidence on COVID-19 vaccination indicates that **the updated vaccines are effective in reducing the risk of severe illness, hospitalization, and death due to COVID-19, although their efficacy against infection varies and wanes over time**. The updated mRNA vaccines, which target the XBB.1.5 strain, have shown about 54% effectiveness against symptomatic infection in the short term. However, their effectiveness decreases over several months, especially against newer variants like JN.1. Nevertheless, these vaccines provide sustained protection against severe disease, with approximately 80-90% effectiveness in preventing hospitalization and death for up to six months post-vaccination. Even after a year, the vaccines can provide around 50-60 % effectiveness against severe disease. **Protein Subunit Vaccine (Novavax) updated vaccine also targets the XBB.1.5 strain and has shown promising results in generating neutralizing antibodies**. While exact figures on its efficacy against infection are less well-documented compared to mRNA vaccines, it is expected to offer similar levels of protection against severe outcomes. **The Novavax vaccine has demonstrated about 90% effectiveness in preventing severe disease shortly after vaccination, maintaining robust protection for several months**. The additional benefit of bivalent booster vaccines - compared to one or two monovalent booster vaccinations or compared to the primary course alone - in the prevention of SARS-CoV-2 Omicron infection appears to be small, especially in persons with previous Omicron infection, whereas modest to moderate protection from vaccination with bivalent BA.4-5 or BA.1 mRNA-booster vaccines as a fourth dose against COVID-19-associated illness and hospitalization has been reported (Sane Schepisi et al., 2023).

Conclusions

The analysis of COVID-19 VE and safety across different types, including mRNA and protein subunit vaccines, reveals a nuanced landscape of vaccine performance. Both mRNA and protein subunit vaccines have demonstrated strong protection against severe disease, hospitalization, and death, although their effectiveness against infection itself wanes over time. The waning effectiveness of COVID-19 vaccines over time is influenced by multiple interrelated factors. Key determinants include the time elapsed since vaccination, with antibody levels generally declining over months; the evolution of new viral variants that may partially evade vaccine-induced immunity; and individual characteristics such as age, health status, and genetic factors affecting immune response. Level of viral exposure in the community, and the persistence of different types of immunity (antibody-mediated vs. T-cell) contribute to the complex picture.

Across various studies and real-world data, mRNA vaccines **have consistently shown high efficacy in preventing severe outcomes**. During the Omicron variant surge, mRNA vaccines required additional booster doses to maintain high levels of protection, with **efficacy against severe disease remaining around 80-90% up to six months post-vaccination**. This robustness in efficacy is particularly notable in elderly populations, where mRNA vaccines showed the highest efficacy among evaluated vaccines. However, mRNA vaccines were associated with higher incidences of local and systemic adverse events compared to inactivated vaccines**, highlighting a trade-off between efficacy and tolerability**. Protein subunit vaccines, such as the updated Novavax vaccine targeting the XBB.1.5 strain, have also shown promising results. These vaccines generated significant neutralizing antibodies and demonstrated about 90% effectiveness in preventing severe disease a few weeks after vaccination, maintaining strong protection for several months. **While detailed VE data against symptomatic infection for protein subunit vaccines are less extensive, their effectiveness in preventing severe outcomes is comparable to that of mRNA vaccines**. **The hybrid immunity conferred by natural infections and vaccination provides the greatest and longest-lasting protection against COVID-19**.

The heterologous vaccine regimens (combining different types of vaccines) have been found to induce stronger immune responses and higher effectiveness (suggesting that no single vaccine type is universally superior) compared to homologous regimens (using the same vaccine type). For instance, schedules combining adenovirus-vectored vaccines with mRNA vaccines showed enhanced immunogenicity and effectiveness against COVID-19. **This suggests that while mRNA vaccines are highly effective on their own, their combination with other vaccine types and natural infections can further improve immunogenicity and protection**. These heterologous schedules would add a level of complexity to vaccine schedules that may not warrant the implementation of such a schedule, given that hybrid immunity is present in an overwhelmingly large proportion of the population. In the future, if this approach is cost-effective and feasible, there is no reason not to mix vaccines according to availability to achieve the same or even better protection. This comprehensive understanding **underscores the importance of continued adaptation and booster updates to address emerging variants and maintain high levels of immunity in the population**.

At present, mRNA vaccines may still have an edge over other platforms in terms of availability, production capacity and ease of adaptation to new variants, but less more in terms of VE and safety profile.

Recommendations

In view of the literature review and conclusions, the SHC is of the opinion that COVID-19 homologous (same vaccines) or heterologous (vaccines from different platforms) vaccine regimens with vaccines adapted to the circulating variant are scientifically sound, interchangeable and therefore usable-acceptable in Belgium in terms of VE and safety.

Since the main objective is to have **a winter vaccination campaign with the highest possible coverage of all at-risk groups for the main winter respiratory diseases** (Influenza, COVID-19, RSV, Pneumococcus), the choice of COVID-19 vaccines to be offered is left to the discretion of the Belgian authorities, depending on availability and Belgian and European logistical constraints for the purchase and distribution of the most adapted vaccines.

5 Main adverse effects of COVID-19 vaccines

Since the beginning of the COVID-19 pandemic, **approximately 13.5 billion doses of COVID-19 vaccines** have been administered globally as of September 2024. Thousands of scientific publications are referenced in PubMed concerning COVID-19 Vaccines[4]. These publications cover a wide range of topics including VE, safety, side effects, variants and immune responses, reflecting the rapid and expansive research efforts globally. With billion doses administered, hundreds of scientific articles evaluated by the NITAG and probably the most intense post-marketing surveillance of any vaccine (or drug), **the experts of the SHC affirm with high confidence that these COVID-19 vaccines approved by EMA and currently on the European and Belgian market are safe and effective, including for pregnant women and immunocompromised patients**. Like for all medicines, COVID-19 vaccines have side effects, and certain scientific uncertainties remain. Nevertheless, **The benefit/risk balance of currently marketed COVID-19 vaccines is favorable especially for at risk groups**. These side effects (serious in a few rare cases) are far outweighed by the multiple benefits of COVID-19 vaccination against severe forms of the disease (hospitalizations ; ICU admissions ; etc.) and deaths in at-risk groups, as defined in this report.

In general, the most common adverse effects observed after COVID-19 vaccination include injection site reactions, headache, fever, fatigue, and muscle pain (Monadhel et al., 2024). Severe but rare adverse effects include anaphylaxis and facial paralysis (Mirza et al., 2025). Diagnostic and treatment of the particular or suspected side effects of COVID-19 vaccines are highlighted in recent reviews (Padilla-Flores et al., 2024; Panos et al., 2024; Finsterer et al., 2024; Arabzadeh Bahri et al., 2024; Ammirati et al., 2024; Censi et al., 2024; Zou et al., 2024; Handunnetthi et al., 2024).

For mRNA vaccines (such as Comirnaty® and Spikevax®), the most severe but rare side effects are **anaphylaxis**, **myocarditis** and **pericarditis**, particularly in younger males (Buoninfante et al., 2024; Kitano et al., 2025). On the other hand, adenovirus vector vaccines (such as Vaxzevria® and JCovden®, withdrawn in the EU) have been associated with rare cases of vaccine-induced thrombotic thrombocytopenia – VITT(Cheda et al., 2024), Guillain-Barré syndrome, transverse myelitis and venous thromboembolism (*reference for all these SAE are the product information/SmPC for each vaccine).*

There has been some concern about the influence of COVID-19 vaccines on menstrual health, and this has been extensively studied. Of note, temporary and light perturbation of the menstrual function, **without impact on long term fertility**, have also been observed with natural virus infections, stress and others vaccines (McInerney et al., 2017 – Human Papillomavirus – HPV vaccine). It is therefore unsurprising that COVID-19 vaccine can be associated with temporary changes in **menstrual characteristics (cycle length and flow) and menstrual pain** (without impact on long term fertility) or abnormal vaginal bleeding in post-menopausal individuals (Peinemann et al., 2024; Shahrani et al., 2024; Dorjee et al., 2025; Payne et al., 2024).

Concerning the impact of COVID-19 vaccination and fertility, **there is no scientific evidence that the vaccines have a negative, major and long term effect on fertility of women and men**. Recent systematic review, meta-analysis or review **are very reassuring on this subject** (Valdes et al., 2024 ; Ciapponi et al, 2023 and 2024 ; Wang et al., 2023 ; Zaçe et al., 2022). Some effects on fertility that were attributed to COVID-19 vaccines are also observed with stress, pollution, others diseases, natural viral infections and other vaccines (McInerney et al., 2017 - HPV). Due to the specific attention to COVID-19 vaccine and the massive post-marketing surveillance, some effects on women and men could have been specifically

[4] https://pubmed.ncbi.nlm.nih.gov/?sort=date&term=%22COVID-19+Vaccines%22%5BMesh%5D

highlighted in the literature (and related by social media with intentional or unintentional misinformation) but **without a clear and well proved association with COVID-19 vaccination**.

In conclusion, temporary changes in menstrual cycles have been reported after vaccination, these changes are minor and short-lived. **As of now, no vaccine has been shown to have a lasting or significant negative effect on women and men fertility**. Any menstrual changes or sperm parameters reported are temporary and **do not affect one's ability to conceive**.

EMA and the EU Member States continue to closely monitor the safety of COVID-19 vaccines (for common and particular side effects see Safety of COVID-19 vaccines | European Medicines Agency (EMA) (europa.eu) – for suspected side effects see European database of suspected adverse drug reaction reports (adrreports.eu)). **Any person that experiences possible adverse effects after vaccination should consult a healthcare provider**. Patients and healthcare providers **are encouraged to declare these effects to the authorities in charge of post-marketing surveillance**, as is always recommended for any concerns about vaccination. Reporting of adverse reactions can be done directly to www.notifieruneffetindesirable.be or www.eenbijwerkingmelden.be.

In the recent literature, there are also publications that link certain pathologies to COVID-19 and/or vaccination. Most of these publications are case-series lacking a comparison group. These associations are monitored by the competent pharmacovigilance authorities. At this stage, a formal causal link has not been established between any of these pathologies and vaccination against COVID-19. All the authors of these publications agree that despite these data, the benefit/risk balance still remains strongly in favour of vaccination (Arepalli et al., 2025; Gannamaneni et al., 2025; Etemadifar et al., 2024; Yang et al., 2024; Zou et al., 2024; Padhi et al., 2025; Khatami et al. 2025; Martora et al., 2024; Efe et al., 2025; Cahuapaza-Gutierrez et al., 2024; Ragni et al., 2025; Verrienti et al., 2024).

6 Pregnant women and COVID-19 vaccination for 2024-2025

In 2021, the Belgian NITAG was one of the first expert groups to strongly recommend systematic vaccination of all pregnant women or women wishing to become pregnant against COVID-19 in the pre-Omicron period (CSS 9622, 2021). Since then, in addition to the vaccinations already recommended by NITAG in Belgium for pregnant women (SHC 8754, 2020), vaccination against RSV has also been added to the list of recommended vaccines (SHC 8754, 2023). Pending an ongoing revision of SHC 8754, which should define all recommended vaccinations in a single document and a comprehensive vaccination calendar for pregnant women, as well as an order of priority, the SHC has reviewed the literature concerning COVID-19 vaccination for pregnant women for the 2024-2025 season. By this way, we hope to provide practitioners and pregnant women a review of the most recent publications on the subject, and to enable them to make an informed decision based on other vaccine priorities to protect pregnant women and/or the fetus.

The majority of European NITAGs (ECDC communication) and international publications continue to strongly recommend COVID-19 vaccination for all pregnant women. This vaccination is safe and effective to protect this group against severe forms of the disease and adverse events for the fetus. Nevertheless, essentially based on new epidemiological data during the Omicron period, some European countries, including The Netherlands (Vaccineren tegen corona tijdens zwangerschap | RIVM ; https://www.gezondheidsraad.nl/onderwerpen/vaccinaties/documenten/adviezen/2024/03/27/advies-covid-19-vaccinatie-in-2024) have taken a different stance and no longer include COVID-19 vaccination of all pregnant women in a systematic way in their 2024-2025 recommendation "… *In the current situation, the committee no longer recommends that vaccination against COVID-19* ***be offered by default to all pregnant women****. Pregnant women from the medical risk groups remain eligible for vaccination*..." (*GR, 2024 - advies COVID-19-vaccinatie in 2024, Publicatienummer: 2024/06*).

Concerning the literature review,

Malik and collaborators (2024) identified 76 articles, of which 3 fulfilled eligibility criteria. Included studies were of moderate and high quality. The social media platforms investigated included Facebook, Google Searches, Instagram, Reddit, TikTok, and Twitter. **Misinformation on COVID-19 vaccination during pregnancy was related to concerns regarding vaccine safety, and its association with infertility**. Misinformation was increased due to lack of content monitoring on social media, exclusion of pregnant women from early vaccine trials, lack of information from reputable health sources on social media, and others. Suggested solutions were directed at pregnancy care providers (PCPs) and public health/government. They suggest to fight the misinformation by (i) integrating COVID-19 vaccination information into antenatal care, (ii) PCPs and public health should increase their social media presence to disseminate information, (iii) address population-specific vaccine concerns in a culturally relevant manner, and others. Increased availability of information from reputable health sources through multiple channels could increase COVID-19 vaccine uptake in the pregnant population and help combat misinformation (Malik et al., 2024 ; De Brabandere et al., 2023). Training healthcare providers to promote vaccinations during pregnancy is crucial and could be enhanced by utilizing mobile health technologies (Valdes et al., 2024 ; Razai et al., 2023 ; Devera et al., 2024 ; Amaral et al. 2023).

Worldwide, **the prevalence of COVID-19 vaccine acceptance in pregnant women was 53.46%**, which was much lower than the COVID-19 vaccination acceptance in the general population and not so bad compared to other vaccinations recommended during pregnancy. Therefore, necessary interventions should be taken to increase the acceptance of the vaccine, address safety concerns and educate about it (Azami et al., 2022 ; Bhattacharya et al., 2022).

In United States, COVID-19 vaccine nonacceptance in pregnant women is associated with Hispanic ethnicity and Black race, while acceptance is associated with Asian race, college education or more, at least part-time employment, and acceptance of the influenza vaccine. Future COVID-19 vaccination campaigns can target identified subgroups of pregnant women who are less likely to accept vaccination (Patel et al., 2024 ; Moriarty et al., 2024).

Vaccination during any trimester is considered safe in pregnant women (Askary et al., 2023 ; Ding et al., 2023 ; Nicolaidou et al., 2023 ; Wu et al., 2023 ; Shafiee et al., 2023 ; Wang et al., 2023). Wang and collaborators (2024) aimed to estimate the associations between coronavirus disease 2019 (COVID-19) vaccination during pregnancy and the risks of adverse perinatal outcomes. They performed a literature search in PubMed, Web of Science and Embase to identify eligible studies published up to 24 September 2023, yielding 39 included studies. Pooled relative risks (RRs) with 95% confidence intervals (CIs) were calculated with a random effects model. **The pooled results showed that COVID-19 vaccination during pregnancy (any type or dose of COVID-19 vaccination during any trimester) was not associated with an increased risk of adverse perinatal outcomes**. In particular, **COVID-19 vaccination in the third trimester was associated with a decreased risk of preterm birth** (<37 weeks) (RR 0.85 [95% CI 0.74 to 0.98]), 5-min Apgar <7 (RR 0.87 [95% CI 0.78 to 0.97]) **and NICU admission** (RR 0.90 [95% CI 0.86 to 0.95]). The inverse associations were also found in analysis of **one-dose vaccination during pregnancy and the risk of miscarriage** (RR 0.83 [95% CI 0.72 to 0.96]) and preterm birth (<37 weeks) (RR 0.90 [95% CI 0.80 to 1.00]) **and two-dose vaccination during pregnancy and the risk of NICU admission** (RR 0.86 [95% CI 0.76 to 0.96]). **COVID-19 vaccination during pregnancy does not increase the risk of negative outcomes for the mother or baby** (Wang et al., 2024 ; Askary et al., 2023 ; Shafiee et al., 2023 ; Zhang et al., 2023 ; Hagrass et al., 2022 ; Prabhu et al., 2023). Most studies showed no significant difference in short-term adverse effects between vaccinated and non-vaccinated women and their fetuses (Ciapponi et al., 2023), however, the literature is insufficient to evaluate possible long-term adverse effects. **Available evidence supports the safety of administering SARS-CoV-2 vaccines to pregnant women, but further systematic reviews and meta-analyses are essential especially for non mRNA vaccines** (Kontovazainitis et al., 2023 ; Ding et al. 2023 ; Wu et al., 2023 ; Konje et al., 2023). **Vaccination against COVID-19 is not associated with different fertility outcomes in patients undergoing assisted reproductive technologies** (Chamani et al., 2024; Kong et al., 2024). The administration of vaccinations should be advised and encouraged to protect the mothers with antibodies and the neonates by the passive transmission of antibodies through the placenta and breast milk (Li et al., 2024; Deese et al., 2025). **This is a significant reason for not stopping breastfeeding even in case of COVID-19 infection**. With adherence to proper hygiene methods, breastfeeding is recommended to be continued as the benefits greatly outweigh the risks (Ahmad et al., 2024 ; Ketabi et al., 2023).

In a recent Meta-Analysis, **the authors have evaluated sixty-seven studies covering 1,813,947 women**. Overall, in test-negative design studies, pregnant women fully vaccinated with any COVID-19 vaccine had 61% reduced Odds Ratio (OR) of SARS-CoV-2 infection during pregnancy (OR 0.39, 95% CI 0.21 to 0.75; 4 studies, 23 927 women; I2=87.2%) and 94% reduced odds of hospital admission (OR 0.06, 95% CI 0.01 to 0.71; 2 studies, 868 women; I2=92%). In adjusted cohort studies, the risk of hypertensive disorders in pregnancy was reduced by 12% (RR 0.88, 95% CI 0.82 to 0.92; 2 studies; 115 085 women), while caesarean section was reduced by 9% (OR 0.91, 95% CI 0.85 to 0.98; 6 studies; 30,192 women). They observed an 8% reduction in the risk of NICU admission (RR 0.92, 95% CI 0.87 to 0.97; 2 studies; 54 569 women) in babies born to vaccinated versus not vaccinated women. In general, vaccination during pregnancy was not associated with increased risk of adverse pregnancy or perinatal outcomes. Pain at the injection site was the most common side effect reported (77%, 95% CI 52% to 94%; 11 studies; 27,195 women). **They have concluded that**

COVID-19 vaccines are effective in preventing SARS-CoV-2 infection and related complications in pregnant women (Fernández-García et al., 2024).

In an even more recent Meta-Analysis that is grading the scientific evidence published in Oktober 2024, Ciapponi and collaborators included 177 studies involving 638,791 participants from 41 countries. Among the 11 types of COVID-19 vaccines identified, the most frequently used platforms were mRNA (154 studies), viral vector (51), and inactivated virus vaccines (17). **Low to very low-certainty evidence** suggests that **vaccination may result in minimal to no important differences compared to no vaccination in all assessed maternal and infant safety outcomes** from 26 fewer to 17 more events per 1,000 pregnant persons, and 13 fewer to 9 more events per 1,000 neonates, respectively. They found **statistically significant reductions in emergency cesarean deliveries (9%) with mRNA vaccines, and in stillbirth (75-83%) with mRNA/viral vector vaccines**. **Low to very low-certainty evidence** suggests that vaccination during pregnancy with mRNA vaccines **may reduce severe cases or hospitalizations in pregnant persons with COVID-19** (72%; 95% CI 42-86), **symptomatic COVID-19** (78%; 95% CI 21-94), and **virologically confirmed SARS-CoV-2 infection** (82%; 95% CI 39-95). Reductions were lower with other vaccine types and during Omicron variant dominance than Alpha and Delta dominance. Infants also presented with **fewer severe cases or hospitalizations** due to COVID-19 and laboratory-confirmed SARS-CoV-2 infection (64%; 95% CI 37-80 and 66%; 95% CI 37-81, respectively). In conclusion, they found **a large body of evidence supporting the safety and effectiveness of COVID-19 vaccines during pregnancy**. While the certainty of evidence is not high, it stands as the most reliable option available, given the current absence of pregnant individuals in clinical trials. Results are shared in near real time in an accessible and interactive format for scientists, decision makers, clinicians, and the general public. This living systematic review highlights **the relevance of continuous vaccine safety and effectiveness monitoring, particularly in at-risk populations for COVID-19 impact such as pregnant persons, during the introduction of new vaccines**.

Cruz-Cavalente and collaborators (2024) investigate the impact of COVID-19 infection on maternal characteristics and obstetric and neonatal outcomes in **a cohort of women in labor previously vaccinated who tested positive for SARS-CoV-2 infection**, compared to aged-matched healthy controls. A retrospective case-control study was conducted among 66 women in labor. Clinical data were obtained from medical records. The attendance rates at childbirth and parenting classes, as well as the implementation of a birth plan, were significantly lower in the COVID-19 infection group (6.1% vs. 48.5%, <0.001; 6.1% vs. 33.3%, p = .005, respectively). **Women with COVID-19 had a higher prevalence of prolonged postpartum hospital stay** (33.3% vs. 9.1%, p = .016), and **significantly higher prevalence of spontaneous preterm birth** (27.3% vs. 1.09%, p = .006). Breastfeeding within the first 24h was also lower in women with COVID-19 (72.7% vs. 97.0%, p = .006). Maternal characteristics and neonatal outcomes **are still influenced by COVID-19 infection in vaccinated women**. Complications include spontaneous preterm birth, prolonged postpartum hospital stay, and lack of breastfeeding within the first 24 h (Cruz-Calvente et al., 2024).

Omicron exhibits reduced pathogenicity in general population than the previous SARS-CoV-2 variants. However, the severity of disease and pregnancy outcomes of Omicron infection among pregnant women **have not yet been definitively established**. Meanwhile, substantial proportions of this population have doubts about the necessity of vaccination given the reports of declining efficacy of COVID-19 vaccines. Herein, He and collaborators (2023) comprehensively discuss the clinical outcomes of infected pregnant women during the Omicron period and summarize the available data on the safety and efficacy profile of COVID-19 vaccination. The results found that the incidence of moderate and severe disease, maternal mortality, pregnancy loss, preterm delivery, stillbirth, preeclampsia/eclampsia, and gestational hypertension **during the Omicron period are similar to those during the Pre-Delta period**. In view of the effects of mass vaccination and previous natural infection on disease severity,

the virulence of Omicron in pregnant women may be comparable to or even higher than that of the Pre-Delta variant. Moreover, the currently approved COVID-19 vaccines are safe and effective for pregnant women. Particularly, those who received a second or third dose had significantly less severe disease with little progression to critical illness or death compared with those who were unvaccinated or received only one dose. **Therefore, pregnant women should still strictly follow preventive measures to avoid infection and receive the COVID-19 vaccine in a timely manner** (He et al., 2023 ; Piekos et al., 2022 ; Cardemil et al., 2024 ; Bednarek and Laskowska, 2024 ; Torche et al., 2023 ; Simeone et al., 2023).

Placentitis due to COVID-19 infection: Of the 180 placentas analyzed in this study, 37,2% showed histopathological lesions and in 12.8% an immunohistochemically proven SARS-CoV-2 placentitis was present. SARS-CoV-2 immunohistochemical positivity **was only seen in non-vaccinated mothers**. The risk of fetal demise was more than 5 times higher for non-vaccinated mothers and their placentas showed significantly more syncytiotrophoblast necrosis and chronic histiocytic intervillositis compared to vaccinated mothers (both $p < 0,001$). **Maternal vaccination was associated with a reduced risk of SARS-CoV-2 placentitis and stillbirth**. These studies provides new evidence of the protective effect of vaccination on the placenta (Zels et al., 2024 ; Ghesquiere et al., 2024). An other recent study suggest that maternal COVID-19 infection (even in vaccinated women) imparts serious but rare risks to placental health and stillbirth. Despite the many studies conducted to understand the impact of COVID-19 on placental, fetal and neonatal health to date, **key knowledge gaps remain**. Most scientific studies lack the comprehensive reporting of clinical outcomes and laboratory testing of the placenta and fetus recommended by consensus workshops offering standardized definitions of placental infection. The use of classification systems to aid in categorization of the confidence in a case of vertical transmission should also be adopted in larger studies, particularly with newly emerging virulent SARS-CoV-2 strains, to identify potential changes in risk for vertical transmission. The changing landscape of comprehensive information regarding the immune response to different SARS-CoV-2 variants, the effects of vaccination, including the number of doses administered, and the timing of infection during the pregnancy. As placental histopathologic findings have been studied using retrospective case series with varying control groups and COVID-19 disease states, **it is not possible to determine the frequency of specific pathologic features in the placenta and adverse perinatal outcomes** like spontaneous abortion, stillbirth, or hypertensive diseases in pregnancy. It also remains unknown whether disease acquisition during specific trimesters imparts a greater risk for placental pathology, but current evidence **suggests that maternal COVID-19 in the first trimester may confer a greater risk of spontaneous abortion**. There are very few large cohorts of placental pathology associated with COVID-19 and the field would benefit from ongoing studies in different populations with careful attention to case definitions to capture the impact of emerging SARS-CoV-2 strains on placental health (Li et al., 2024).

Completion of a COVID-19 vaccination series during pregnancy **effectively reduces COVID-19 hospitalization among infants less than 6 months of age**. The effectiveness of maternal vaccination against hospitalization for Covid-19 among infants was 52% (95% confidence interval [CI], 33 to 65) overall, 80% (95% CI, 60 to 90) during the delta period, and 38% (95% CI, 8 to 58) during the omicron period. Effectiveness was 69% (95% CI, 50 to 80) when maternal vaccination occurred after 20 weeks of pregnancy and 38% (95% CI, 3 to 60) during the first 20 weeks of pregnancy (Halasa et al., 2022). **The dynamics of transplacental transfer of maternal vaccine-induced antibodies, and their persistence in infants** at 2, 6, 9, and 12 months, have implications for new vaccine development and optimal timing of vaccine administration in pregnancy (Pérez-Latorre et al., 2024). Lopez and collaborators (2024) evaluated anti-COVID antibody IgG subclass, Fc-receptor binding profile, and activity against wild-type Spike and RBD plus five VOCs in 153 serum samples from 100 infants. Maternal IgG1 and IgG3 responses persisted in 2- and 6-month infants to a greater extent

than the other IgG subclasses, with high persistence of antibodies binding placental neonatal Fc-receptor and FcγR3A. Lowest persistence was observed against the Omicron RBD-specific region. Maternal vaccine timing, placental Fc-receptor binding capabilities, antibody subclass, fetal sex, and VOC all impact the persistence of antibodies in infants through 12 months of age (Lopez et al., 2024). **A booster dose during pregnancy** significantly increased maternal and cord blood binding and neutralizing antibody levels, including against Omicron BA.1. Findings support the use of a booster dose of COVID-19 vaccine during pregnancy (Munoz et al., 2023).

Conclusions

Pregnant women at any stage of pregnancy are also at greater risk of COVID-19 and vaccination has been proven to be safe in pregnancy and to protect the infant (SHC 9622, 22/04/2021; Properzi et al., 2024). The review of the recent literature on COVID-19 vaccination in pregnant women **indicates a clear and continued recommendation for vaccination**. The prevalence of **misinformation** regarding vaccine safety and fertility concerns on social media, suggest that integrating vaccination information into antenatal care and increasing the presence of healthcare providers on social media could help combat this misinformation. COVID-19 **vaccine acceptance among pregnant women worldwide is only 53.46%**, which is significantly lower than the general population but not so bad compared to other vaccinations recommended during pregnancy. Some identified demographic factors influencing vaccine acceptance, suggest targeted interventions for subgroups with lower acceptance rates. **Numbers of recent reviews and studies have consistently shown that COVID-19 vaccination during pregnancy is safe and not associated with adverse perinatal outcomes**. **On the contrary, vaccination has been linked to a decreased risk of preterm birth, low Apgar scores, NICU admissions and risk of hospitalization for COVID-19 infection during the first months of life**. **Further, vaccinated pregnant women have a reduced risk of SARS-CoV-2 placentitis and stillbirth, emphasizing the protective effects of vaccination on both maternal and fetal health**. While concerns about the impact of vaccination on fertility and maternal immune activation were noted, the available evidence does not support **significant adverse effects** of COVID-19 vaccination on women and men fertility. Vaccination is considered safe and effective during any trimester (probably the best effect is vaccination during the third trimester) and does not negatively impact fertility outcomes. Furthermore, maternal **vaccination benefits newborns through passive antibody transmission via the placenta and breast milk** and **breastfeeding remains recommended even in cases of maternal COVID-19 infection**. Despite the probably reduced pathogenicity of the Omicron variant and the growing hybrid immunity in the population (natural infections and vaccination), **several authors argue that vaccination remains crucial for pregnant women to prevent severe disease outcomes, which remain comparable to or even worse than those of earlier variants**. Thus, continuous adherence to preventive measures and timely COVID-19 vaccination for pregnant women is still essential. **The collective evidence strongly supports the safety and efficacy of COVID-19 vaccination for pregnant women**. **The benefits of vaccination, including reduced risks of severe disease, adverse perinatal outcomes, and SARS-CoV-2 placentitis, far outweigh any potential risks.**

Recommendations

Based on Belgian epidemiological data, a review of the literature, and the conclusions drawn about COVID-19 vaccination in pregnant women, the SHC **expresses a clear preference for voluntary, individualized vaccination during pregnancy**. The pregnant women's decision should be guided by a **thorough assessment of the benefit-risk balance**, conducted in consultation with the healthcare provider overseeing the pregnancy.

In making this decision, both the healthcare provider and the pregnant woman **should consider all vaccinations recommended by the NITAG** (SHC 8754, 2020; SHC 9760, 2023; SHC 9831, 2024[5]). **To facilitate vaccine access, authorities must ensure that COVID-19 vaccines are available to pregnant women year-round, not just during specific seasons**.

Several factors may explain the variations in risk assessment and recommendations for pregnant women across countries and continents. These include rising hybrid immunity (from natural infections combined with primary vaccination and booster doses), the reduced severity of the Omicron variant due to strong herd immunity, differences in healthcare organization in Europe, lower rates of high-risk pregnancies (influenced by demographics, socioeconomic factors, obesity, etc.), and a lower burden of severe COVID-19 (hospitalizations and ICU admission) in pregnant women and/or their newborn.

Taking account of these and pending an ongoing revision of SHC-8754, which should define all recommended vaccinations in a single document and a comprehensive vaccination calendar for pregnant women, as well as an order of priority, the Belgian NITAG recommends the following for pregnant women in Belgium (season 2024-2025):

- Pregnant women**, at any stage of pregnancy, with comorbidities OR those expected to have a high-risk pregnancy OR those not yet infected/vaccinated** MUST receive COVID-19 vaccination as a high priority.

- Healthy pregnant women **without comorbidities or an anticipated high-risk pregnancy** MAY OPT for COVID-19 vaccination on an individual basis. This decision should involve a discussion with a healthcare provider, taking into account priorities and risk factors for all vaccinations recommended by NITAG (SHC 8754, 2020 ; SHC 9760, 2023 ; SHC 9831, 2024).

[5] https://www.hgr-css.be/en/report/8754/maternal-immunisation (All)
https://www.hgr-css.be/en/report/9831/vaccination-against-seasonal-influenza (Flu)
https://www.hgr-css.be/en/report/9760/prevention-against-rsv-disease-in-children (RSV)

7 Conclusions and recommendations of previous advisory report and are still valid in view of the recent literature review carried out in 2025

Communities with at-risk groups

Residents of Long Term Care Facilities (LTCF) are also at increased risk, making up less than 1% of the US population but accounting for more than 35% of all COVID-19 deaths.

Comorbidities (SHC 9618, 2021)

Risk of severe outcomes is increased in people of all ages **with certain underlying chronical medical conditions** and in people who are 50 years and older, with risk increasing substantially at ages > 65 years (CDC, 2019[6]; SHC 9618, 2021; Stouten et al., 2023 – Sciensano).

Patient with immunosuppression due to disease or treatment (SHC 9691, 03/03/2022) are at greater risk with an potential reduced VE.

If certain patients need to have their vaccination schedule adapted from that recommended by the EMA, this must remain the strict responsibility of the physician in charge of the specific follow-up of these at-risk patients, and does not fall within the specific scope of this report (KRINKO, 2022; Tan et al., 2023; Razonable et al., 2024; Sharifi Aliabadi et al., 2024; Bytyci et al., 2024; Chedid et al., 2024; Jiang et al., 2024; Merli et al., 2024; Liu et al., 2024; Hua et al., 2024; Harandi et al., 2024; Rubin et al., 2024; Perencin et al., 2024; Olivieri et al., 2025).

Obesity and Diabetes

Obesity (Body Mass Index (BMI) ≥ 40 kg/m2) **and Diabetes** are others well-known risk factors for COVID-19 severe outcomes (Ho et al., 2020; Yang et al., 2020; Földi et al., 2020; Mahamat-Saleh et al., 2021; Pranata et al., 2021; Yuan et al., 2024; Fatoke et al., 2025; Ronca et al., 2025).

Children and adolescents

For children and adolescents regarding Omicron, the SHC can conclude that data on **VE against infection, transmission, hospitalization** show a moderate to low effect on a shorter period of time but a positive effect of a first booster dose in children and adolescents (Fleming-Dutra et al., 2022; Katz and Edwards, 2022; Dorabawila at al., 2022). Secondly, data on **hospitalizations in Belgium** show very low numbers of hospitalizations and deaths for this age group in Belgium. Thirdly, **Multisystem inflammatory syndrome in children (MIS-C)** is less important and less severe with Omicron (Holm et al., 2022; Levy et al., 2022; Wang et al., 2022). Finally, **long Covid** seems less frequent with Omicron than with previous VOCs in the adult population (Antonelli et al., 2022; Xie et al., 2024). With all these data, systematic vaccination of children and adolescents against COVID-19 (and flu) isn't a high priority for the Belgian NITAG.

VE of mRNA vaccines during Omicron

VE of mRNA vaccines against severe outcomes caused by Omicron **remains high, with continued strong protection against death, Intensive Care Unit (ICU) and hospitalisations 6 months after receiving a booster, despite waning.** In all groups, VE against symptomatic infection starts lower, wanes more rapidly and to a much larger extend. Vaccines adapted to Omicron BA4/5 strains are **at least as effective as earlier versions on**

current circulating strains and more data will be available during coming years to asses an eventual clinical superiority (Wang et al., 2022; Collier et al., 2022; Offit, 2023; Cromer et al., 2023; Xu et al., 2023; Link-Gelles et al., 2022; Tenforde et al. 2022; Surie et al., 2022; Zou et al., 2022; Muik et al., 2022).

Compared VE of different COVID-19 vaccine platforms

The analysis of COVID-19 VE and safety across different types, including mRNA and protein subunit vaccines, reveals a nuanced landscape of vaccine performance. **Both mRNA and protein subunit vaccines have demonstrated strong protection against severe disease, hospitalization, and death**, although their effectiveness against infection itself wanes over time. While detailed VE data against symptomatic infection for protein subunit vaccines are less extensive, **their effectiveness in preventing severe outcomes is comparable to that of mRNA vaccines**.

Heterologous vaccine regimens and hybrid immunity

The heterologous vaccine regimens (combining different types of vaccines) have been found to induce stronger immune responses and higher effectiveness (suggesting that no single vaccine type is universally superior) compared to homologous regimens (using the same vaccine type). For instance, schedules combining adenovirus-vectored vaccines with mRNA vaccines showed enhanced immunogenicity and effectiveness against COVID-19. **This suggests that while mRNA vaccines are highly effective on their own, their combination with other vaccine types and natural infections can further improve immunogenicity and protection.**

The hybrid immunity conferred by natural infections (Zhang et al., 2024) **and vaccination provides the greatest and longest-lasting protection against COVID-19** (Pilz et al., 2022; Goldberg et al., 2022; Suarez et al., 2022; Moore et al., 2025; Zheng et al., 2024; Rodriguez Velásquez S et al., 2024). However, on the data available, the SHC **cannot conclude yet on the duration and impact of a COVID-19 infection (naturally-acquired, vaccine-induced and hybrid immunity) as a clinical protection effect against severe outcomes**. The relationship between levels of antibody titters and the necessity of a booster dose is not yet clear and no (immune) correlate of protection has been defined so far. Furthermore, for cost and practical reasons, it seems for the SHC, unfeasible and unrealistic to study antibody titters to decide on the necessity of a booster at an individual level.

Simultaneous vaccination

Studies show that simultaneous vaccination **is safe and effective** (Lazarus et al., 2021; Toback et al., 2022; Izikson et al., 2022; Moro et al., 2022; Janssen et al., 2022; Tan et al., 2025). However, some studies suggest a reduction in immunogenicity after simultaneous vaccination against COVID-19 and seasonal influenza (Radner et al., 2023). It is not uncommon to see a change (usually a reduction) in the immunogenicity of one of the vaccines administered simultaneously. This has also been reported previously, for example for pneumococcal conjugate vaccines administered at the same time as seasonal influenza vaccine. **The clinical significance of a slight decrease in antibody titers is observed, but probably of no clinical significance**.

Appendix 1 : KRINKO risk groups for IC patients

The allocation concept, suggested by the KRINKO (2022), must not be confused with other clinical risk scores or stages of disease but can help to categorized the risk of infection and the necessity of COVID-19 vaccination for the physicians in charge of the patient (KRINKO, 2022; Tan et al., 2023; Razonable et al., 2024; Sharifi Aliabadi et al., 2024; Bytyci et al., 2024; Chedid et al., 2024; Jiang et al., 2024; Merli et al., 2024; Liu et al., 2024; Hua et al., 2024; Harandi et al., 2024; Rubin et al., 2024; Perencin et al., 2024). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9174886/pdf/HIC-17-07.pdf

Risk group 1 (moderate immunosuppression/-deficiency)

- Neutropenia <0.5x10^9/L; (<500/µL) expected to last up to 10 days (comparable to leukopenia <1x10^9/L; <1,000/µL)
- Up to three months after day 0 of autologous stem cell transplantation (the day the stem cells are returned to the patient)
- Decrease in CD4-positive T-helper cells to <200/µL (caution: normal levels that are commensurate vary with age for children); up to three months after the intensive treatment phase of autologous stem cell transplantation.

Patients with more than one of the features of immunosuppression/-deficiency listed for risk group 1 are assigned to risk group 2.

Risk group 2 (severe immunosuppression/-deficiency)

- Neutropenia <0.5x10^9/L; (<500/µL) for more than 10 days (comparable to leukopenia <1x10^9/L; <1,000/µL)
- Severe aplastic anaemia or macrophage activation syndrome during intensive immunosuppressive therapy
- Up to 6 months after completion of the intensive treatment phase of allogeneic bone marrow or stem cell transplantation (important: severity of GVHD and intensity of ongoing iatrogenic immunosuppression)
- Acute inpatient treatment phase of autologous stem cell transplantation or after solid organ transplantation (until discharge).

Risk group 3 (very severe immunosuppression/-deficiency)

- Intensive treatment phase of allogeneic BMT/PBSCT (until engraftment=regeneration of granulopoiesis)
- Severe grade III or IV GVHD with intensive immunosuppression.

The decision to assign patients who have undergone allogeneic stem cell transplantation to group 3 is ultimately taken by their haemato-oncologists after a review of all findings.

Appendix 2 : IC children and adolescents patients

With immunosuppressive treatment in transplant or auto-immune disease, haemato-oncological disease treatment;

With some primary immunodeficiencies (PID):

- **PID with severe combined immune disorder** - (S)CID or severe lymphopenia (CD4 T cell count < 200);
- PID AND severe lung disease;
- **PID patients who will receive or have received stem cell transplant or gene therapy** < 1 year ago or longer if additional treatment is required;
- **Other PID** namely chronic granulomatous disease (CGD), familial haemophagocytic lymphohistiocytosis (HLH), congenital autoinflammatory diseases (except familial Mediterranean fever FMF), PID and active* immune dysregulation (LRBA, NFKB1, NFKB2, STAT3 GOF, IRAK4, MyD88, STAT2, etc.); **autoimmune or autoinflammatory optic surge during the past year or recently started immunosuppressive medication;*
- **Other serious PID conditions** for which the patient himself was contacted by the treating physician for COVID vaccination;

Severe chronic diseases affecting renal, gastro intestinal, cardiovascular, respiratory or neurological health;

Certain rare conditions (including Down syndrome with associated comorbidities or immunological impairment) with an impact on cardiovascular, respiratory or neurological health. In order to know the rare diseases mainly considered, please refer to the Orphanet list. https://www.orpha.net/consor/cgi-bin/Disease_Search_List.php?lng=EN

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For other NITAG recommendations

https://www.nitag-resource.org/network/map

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).

The following experts were involved in drawing up and endorsing this advisory report. The working group (NITAG meetings of June 2025) was chaired by **David TUERLINCKX** and **Steven CALLENS**. The scientific secretary was Fabrice PETERS. Once the advisory report was endorsed by the NITAG, it was ultimately validated by the Board and by mail by the NITAG on 02 Juli 2025.

BLUMENTAL Sophie	Pediatrics, Infectious Disease Medicine, Vaccinology, Primary Immunodeficiency Diseases, Pneumococcal Infections, Tuberculosis.	ULB, CHIREC
BOIY Tine	Pediatrics, Rare Diseases, Congenital Hereditary and Neonatal Diseases and Abnormalities, Down Syndrome.	UAntwerpen, UZA
CALLENS Steven	Internal Medicine, Infectious Disease Medicine, Emerging Communicable Diseases, Travel Medicine, Vaccinology, Tuberculosis, AIDS-HIV, Ebola, COVID-19.	UGent, UZ Gent
CHATZIS Olga	Pediatrics, Infectious Disease Medicine, Congenital Hereditary and Neonatal Diseases and Abnormalities, Vaccinology.	UCLouvain, Cliniques universitaires Saint-Luc
CORNELISSEN Laura	Obstetrics, Gynecology, Epidemiology, Infectious Disease Medicine, Maternal Health, Public Health.	Sciensano
DAELEMANS Siel	Pediatrics, Infectious Disease Medicine, Pulmonary Medicine, Cystic Fibrosis, RSV, COVID-19.	VUB, UZ Brussel
CHRISTIAENS Thierry	Pharmacology.	CBIP/BCFI, UGent
DOGNE Jean Michel	Pharmacy and pharmacovigilance	U Namur, AFMPS, EMA
FRERE Julie	Pediatrics and infectiology	CHR Citadelle
LEROUX-ROELS Isabel	Vaccinology, infection prevention and microbiology	UZ Gent
MAERTENS Kirsten	Vaccinology and maternal immunization	U Antwerpen

MANIEWSKI-KELNER Ula	Infectiology and travel medicine	ITG-IMT-ITM
SOENTJENS Patrick	Travel medicine, vaccinology, zoonotic diseases, HIV	ITG-IMT-ITM, Defense
SWENNEN Béatrice	Epidemiology and vaccinology	ULB
TUERLINCKX David	Pediatrics and vaccinology	CHU UCL Namur
VAN DAMME Pierre	Epidemiology, vaccinology, infectiology, public health	U Antwerpen
VAN LAETHEM Yves	Infectiology, vaccinology and travel medicine	ex-CHU Saint-Pierre, ULB
WAETERLOOS Geneviève	Quality of vaccines and blood products	Sciensano

The following experts were consulted during the last NITAG meeting on this subject and approved the general conclusions and recommendations. However, they did not participate in the final approval of the complete text by email: Sophie Blumental, Antoon De Schryver, Veerle Vekeman, Nele Alders, Marie-Angélique De Scheerder, Koen Vanden Driessche, Anne Tilmanne, and Julie Spoden.

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

DAEMS Joêl	Directorate Drugs	RIZIV-INAMI
DRAGUEZ Bertrand	Health Inspection Advisor	FPS Health, RMG
PERIN Belinda	General medicine, Vaccinology	AVIQ - ONE
SABBE Martine	Vaccinovigilance and safety of vaccines	AFMPS-FAGG
THEETEN Heidi	Vaccinology	VAZG
TEUGHELS Stefan	Medical Director Domus Medica General medicine, public health, EBM	Domus Medica

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 providers, universities, politicians, consumer organisations, etc.).

In order to receive notification about the activities and publications of the SHC, please contact: info.hgr-css@health.belgium.be.

www.superiorhealthcouncil.be

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