Superior
Health Council

COVID-19 VACCINATION: 2023-2024 VACCINATION STRATEGY FOR THE BELGIAN POPULATION

JUNE 2023
SHC № 9766

.be

Federal Public Service Health, Food Chain Safety and Environment

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Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL no. 9766

COVID-19 Vaccination
2023-2024 vaccination strategy for the Belgian population

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 a mRNA vaccine for the Belgian priority groups during the season 2023-2024.

Conclusions and recommendations approved by the members of the NITAG on 20 April 2023.
Approval of this full version of the advisory report by the NITAG on 01 June 2023.
Advisory report validated by the Council on 07 June 2023[1].

I INTRODUCTION AND ISSUE

On March 21 2023 the president of the Task Force COVID-19 asked advice by email to the Superior Health Council (SHC) and the National Immunization Technical Advisory Group (NITAG) on Coronavirus disease 2019 (COVID-19) vaccination strategy with a mRNA vaccine. The following specific questions were asked:

"1. Are there additional scientific arguments that for certain groups, such as health care workers or immunocompromised people, a new booster can be recommended at an accelerated rate, for example (e.g. before summer)?

2. Can the optimal time for a new booster campaign for risk groups (50+ and co-morbidities) in the autumn already be scientifically specified (e.g. based on the expected epidemiology and experience from previous booster campaigns)?"

In order to answer in time to the first question already asked by mail in November 2022 and in January 2023, the NITAG validated and published an annex to SHC 9721 (2022) which gave an update on the need for additional boosters in late winter or spring 2023. This response was sent by mail (02/02/2023) to the Authorities and can be found via the following link: https://www.health.belgium.be/en/report-9721-covid-19-vaccination-autumn-winter-season-2022-2023.

With the SHC now having access to the latest European Centre for Disease Prevention and Control (ECDC) recommendations and mathematical modelling released on 05/04/2023, the issue was evaluated again by NITAG at the 04/2023 meeting for the 2023-2024 season.

[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.

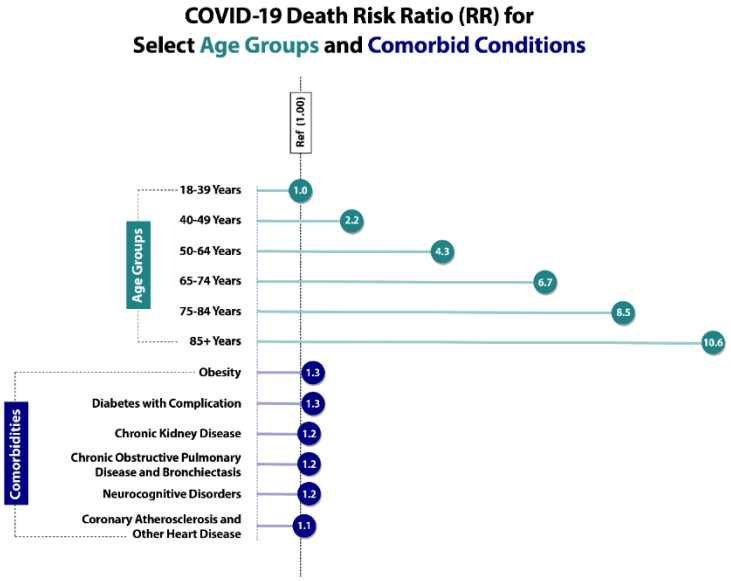
II CONCLUSIONS AND RECOMMENDATIONS

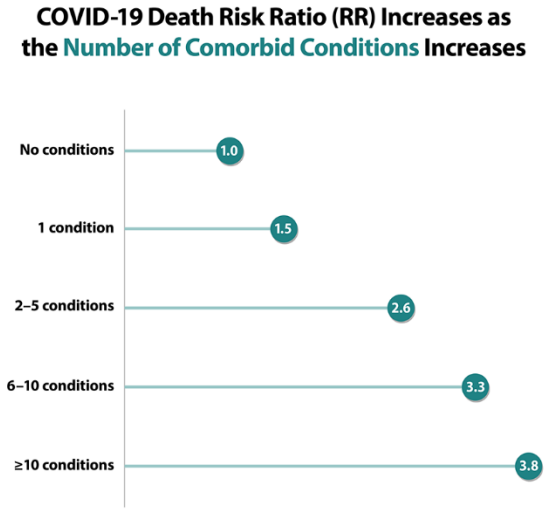
1 CONCLUSIONS

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. Notably, these data include all deaths in the United States that occurred throughout the pandemic, from February 2020 to July 1, 2022, including deaths among unvaccinated individuals.

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

Risk of severe outcomes is increased in people of all ages **with certain underlying medical conditions** and in people who are 50 years and older, with risk increasing substantially at ages > 65 years. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals | CDC





Obesity (Body Mass Index (BMI) ≥ 40 kg/m2) is another well-known risk factor for COVID-19 severe outcomes (Mahamat-Saleh et al., 2021; Pranata et al., 2021; Ho et al., 2020; Yang et al., 2020; Földi et al., 2020).

Pregnant women at any stage of pregnancy (SHC 9622, 22/04/2021) are also at greater risk of COVID-19 and vaccination has been proven to be safe in pregnancy and to protect the infant in more recent systematic reviews and meta-analysis (Askary et al., 2023; Ding et al., 2023; Nicolaidou et al., 2023; Wu et al., 2023; Shafiee et al., 2023).

Patient **with immunosuppression due to disease or treatment** (SHC 9691, 03/03/2022) are at greater risk with an potential reduced VE (KRINKO, 2022; Tan et al., 2023).

Vaccine Effectiveness (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 limited 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** (Wang et al., 2022; Collier et al., 2022; Offit, 2023, Cromer et al., 2023; Xu et al., 2023). More data will be available during coming years to asses an eventual clinical superiority (Link-Gelles et al., 2022; Tenforde et al. 2022; Surie et al., 2022; Zou et al., 2022; Muik et al., 2022).

At this stage of post-vaccination side effect surveillance, **there are no additional safety issues** related to the administration of mRNA vaccine booster doses.

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 mRNA vaccines adapted to current and future strains will be available at the time of recommendation and administration.

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). 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 unprecedented and probably of no clinical significance.

An infection before or after completion of COVID-19 vaccination has a booster effect and the greatest levels of protection against both variants **were provided by hybrid immunity** (Pilz et al., 2022 ; Goldberg et al., 2022 ; Suarez et al., 2022). This has led some countries to postpone the administration of a booster dose in function of a previous infection. 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 titers and the necessity of a booster dose is not yet clear and no (immune) correlate of protection has been defined so far. Furthermore, for practical reasons, it is unfeasible to study antibody titers to decide on the necessity of a booster at an individual level.

For children and adolescents regarding Omicron, actually 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 in the adult population (Antonelli et al., 2022).

Based on the following conclusions from recent EU NITAG (ECDC) and SAGE (WHO) webinars:

- Modelling studies by ECDC suggest that achieving higher vaccination uptake has larger impact than extending eligibility;
- A spring booster for > 80 years has limited impact if uptake is low;
- Global seroprevalence is up to 90% globally;
- A 12 month interval is reasonable for healthy 65+ year old;
- A 2nd booster (although less data available) shows less impact on VE compared to the first booster;
- Number Needed to Vaccinate (NNV) goes up with increased number of boosters;

At the time of drafting these recommendations for the 2023-2024 season, the SHC did not observe in the Belgian epidemiological data and did not found major and concordant scientific publications that could drastically change the already proposed vaccination strategy in 2022-2023. The elements that could require a rapid and urgent adaptation of these recommendations and of the vaccination campaign in Belgium for 2023-2024 would be:

- **new vaccines** just as effective as mRNAs but with longer or broader protection;

- the arrival of a **new variant** with massive immune escape;

- a **drastic loss of vaccine efficacy** on hospitalisations 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 RNA boosters** Analyses are underway at the highest level and according to our information, it does not seem to be moving in this direction at the moment (FDA, 26/01/2023; Offit, 2023; ECDC, 05/04/2023);

- **Strong and consistent scientific evidence** clearly demonstrates the superiority of the adapted RNA BA4/5 vaccines over earlier versions in terms of both level of protection and duration of protection in relation to deaths, intensive care and hospital admissions.

2 RECOMMENDATIONS

1. Timing of Autumn / Winter season 2023 – 2024 COVID-19 vaccination

The timing of COVID-19 booster administration should be guided by logistical considerations and population acceptability, in order to achieve **the highest possible vaccine coverage in at-risk groups for both COVID-19 and Influenza vaccines**.

It is impossible to predict when and how COVID-19 will emerge in the next season, or to estimate its severity and virulence. Based on previous years, the COVID-19 virus circulates weakly throughout the year, 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.

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

In order to best monitor local reactions, we suggest that influenza (right arm) and covid-19 (left arm) vaccines be given systematically in contralateral arms.

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 2023, and from mid-October 2023 for Influenza (SHC 9767, 2023).

It is up to the TF Vaccination 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 both variants **were provided by hybrid immunity**.

2. Minimum interval between mRNA booster doses

As recommended for the first booster (SHC 9683, 2021), the SHC recommends an interval of minimum **6 months** for the administration of an additional mRNA booster dose.

3. Risk groups for Autumn / Winter season 2023 – 2024 COVID-19 vaccination

At present, **the risk groups for vaccination against seasonal influenza and COVID-19 are fairly similar for the elderly and people with comorbidities**, which greatly simplifies simultaneous administration of the two vaccines. However, differences remain at this stage as regards very young children (6 month to 5 years old) and the value of vaccinating them against these two viral diseases[2].

There are also significant differences in terms of VE (greater and more stable for the current COVID-19 mRNA vaccines) and the clinical consequences of the two viruses in the event of severe forms (more severe for COVID-19 in the elderly and with comorbidities, and greater impact of influenza in very young children). This may also influence the risk groups selected for annual vaccination this year, based on scientific hindsight and the data available for both vaccines.

In order to best anticipate the COVID-19 vaccination campaign for Autumn / Winter 2023 - 2024, the SHC recommends the administration of an additional mRNA vaccine for groups 1, 2 and 3 (SHC 9622, 2021; SHC 9618, 2021; SHC 9691, 2022; SHC 9722, 2022 and CDC, 09/02/2023):

- **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 Long Term Care Facilities (LTCF) and nursing homes** (similar to seasonal flu vaccination);
    - All **pregnant women at any stage of pregnancy** (SHC 9622, 22/04/2021 - similar to seasonal flu vaccination);

As pregnancy is a known risk factor for severe disease and vaccination has been proven to be safe in pregnancy and protect the infant, any pregnant woman who has not yet been vaccinated, should be vaccinated **with a complete primary vaccination and 1st booster dose 6 months after the primary vaccination**;

All pregnant women who have already received a booster should receive their additional booster dose in Autumn / Winter season 2023 – 2024, with a minimum interval of **at least 6 months** between the booster doses.

- Any person **with a body mass index (BMI) ≥ 40 kg/m2** (similar to seasonal flu vaccination);

[2] Highlighted in yellow are the elements that differ from those established for seasonal flu vaccination in our opinion 9767.

- Any patient aged 18 years or over **with at least one comorbidity** (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 (similar to seasonal flu vaccination);

  - **hepatic origin** such as cirrhosis, non-alcoholic fatty liver disease, alcoholic liver disease, autoimmune hepatitis, etc. (similar to seasonal flu vaccination);

  - **renal origin** and people receiving dialysis (similar to seasonal flu vaccination);

  - **metabolic origin**, including diabetes type 1 and 2 (similar to seasonal flu vaccination);

  - **cardiac origin** 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 and the risk of severe COVID-19 (CDC, 09/02/2023);

  - **neurologic origin, severe mental health conditions and severe intellectual disability** such as dementia, severe depression, schizophrenia spectrum disorders, etc.

  - **and certain 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

- Any patient aged 18 years or over **with immunosuppression due to disease or treatment** (SHC 9691, 03/03/2022) as patients (similar to seasonal flu vaccination):
  - with an organ or a stem cell transplant (pre-transplant included);
  - who are on immunomodulating drugs;
  - who are undergoing cancer treatment (or have been treated in the last 3 years);
  - with primary immune deficiency (patients with Down syndrome included);
  - who are on renal dialysis;
  - with Human Immunodeficiency Virus (HIV) infection and low CD4 counts (< 200 /mm³).

[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".

The specific situation of individual 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 doctors to amend the risk evaluation in their risk analysis and to recommend the vaccination**.

This 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.
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.

For children and adolescents till 18 years, a **specific focus** should be made on patients with (SHC 9722, 2022) :

Children at risk to be vaccinated against COVID-19

- **Immunocompromised patients**
  - Immunosuppressive treatment in transplant or auto-immune disease, haemato-oncological disease treatment;
  - 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

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

Even though protection **against infection with Omicron** quickly wanes, the SHC would like to enable "care workers" to be protected as much as possible from the risk of severe forms of the disease on an individual basis, minimize as much as possible the risk of transmission to the most vulnerable patients and ensure maximum functioning of the overall health care sector for all patients during the critical winter period (Reichert et al., 2022).

For these reasons, the SHC recommends that these groups be vaccinated with an additional booster for the Autumn / Winter season 2023 - 2024.

The SHC reiterates that the duration of protection against infections and transmission, in the context of Omicron, declines very rapidly over time. **This vaccination strategy complements but does not replace non-pharmaceutical interventions (NPIs)** for people at risk of severe disease in contact with these “persons active in the care sector”.

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 (the "cocoon" vaccination strategy) than:**
    - **Severe and very severe immunocompromised patients** (KRINKO Risk groups 2 and 3).

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9174886/pdf/HIC-17-07.pdf

The specific situation of individual 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 doctors to amend the risk evaluation in their risk analysis and to recommend the vaccination. This 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.

Even though protection **against infection with Omicron quickly wanes**, the SHC would like to minimize the risk of transmission to the most vulnerable patients. The SHC reiterates that, in this specific case of Omicron, cocoon vaccination strategy complements **but does not replace non-pharmaceutical interventions (NPIs)** for people at risk of severe disease.

For people aged 18 to 65y old and not included in groups 1, 2 and 3, a vaccination proposal could be made only **on an individual basis after consultation with the physician**.

A) Particular attention should be paid to people less than 65 years old (and especially after 50 year old):

- **who currently (or former) smoke**

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 risk ratios (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.**

- **with physical inactivity** (Hill et al., 2021);
  Brief Summary of Findings on the Association Between Physical Inactivity and Severe COVID-19 Outcomes

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.

- **who drink alcohol excessively** (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 9438, 2018). 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), 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.**

In conclusion, these people (smokers, physicaly inactive, with substance or alcohol use disorders) could also be vaccinated on the basis of an individual risk analysis and in consultation with their physician, to check that there are no other unknown risk factors.

B) At present, in the context of Omicron 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 of course receive the booster (vaccine safety data are favorable), but this is based solely on an individual decision and not on a scientific recommendation as to the usefulness of this vaccination for them.

4. Additional spring 2024 COVID booster for 85 years old and over and IC patients: NOT recommanded

In light of the new 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 latest ECDC recommendations and mathematical modelling released on 05/04/2023, SAGE and EU NITAG meetings, and the opinion of NITAG experts, the SHC conclude that:

On a voluntary and individual basis and after an individual benefice/risk analysis with the physician, adults aged of 85 years and older and IC patients who would nevertheless like to receive a booster dose **could receive it** if they are clearly informed that it is currently not recommended by NITAG, not clearly supported by the Belgian epidemiological and VE data, that it is an off-label administration and should be administered at least 6 months after the last winter booster injection.

III METHODOLOGY

***Remarks**: the evolution of knowledge and the scientific background behind these conclusions and recommendations can be consulted in our various reports (https://www.health.belgium.be/fr/covid-19-0) and will therefore no longer be the subject of a detailed chapter in this report.*

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, pediatrics, 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.

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 Superior Health Council. This report is based on previous advisory report of the SHC, European Centre for Disease Prevention and Control (ECDC) recommendations and mathematical modelling released on 05/04/2023, 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
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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.
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Once the advisory report was endorsed by the NITAG, it was ultimately validated by the Board.

IV KEYWORDS AND LIST OF ABBREVIATIONS

Keywords

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

List of abbreviations used

AIDS	Acquired immunodeficiency syndrome
AUD	Alcohol Use Disorders
BMI	Body Mass Index
CDC	Centers for Disease Control and Prevention - US
CDK	Chronic Kidney Disease
CGD	Chronic Granulomatous Disease
COPD	Chronic Obstructive Pulmonary Disease
COVID-19	Coronavirus disease 2019
ECDC	European Centre for Disease Prevention and Control - EU
EMA	European Medicines Agency
FDA	Food and Drug Administration - US
FMF	Familial Mediterranean Fever
GINA	Global Initiative for Asthma - INT
HIV	Human Immunodeficiency Virus
HLH	Lymphohistiocytosis
ICU	Intensive Care Unit
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
NITAG	National Immunization Technical Advisory Group - BE
NNV	Number Needed to Vaccinate
NPI	Non-Pharmaceutical Intervention
NVSS	National Vital Statistics System - US at NCHS
PCR	Polymerase Chain Reaction
PID	Primary immunodeficiencies
RR	Risk Ratio
SAGE	Strategic Advisory Group of Experts on Immunization – INT WHO
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SHC	Superior Health Council - BE
SUD	Substance Use Disorders
VE	Vaccine Effectiveness
VOC	Variants Of Concern
WHO	World Health Organization - INT

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Other NITAG recommendations

https://www.nitag-resource.org/resources?f%5B0%5D=diseases%3A15444

1. HAS (France)

https://www.has-sante.fr/jcms/p_3417245/fr/strategie-de-vaccination-contre-la-covid-19-anticipation-des-campagnes-de-vaccination-en-2023

2. Gezondheidsraad (Nederland)

Pas de nouvel avis en 2023 autres que enfants
De Gezondheidsraad en COVID-19 | Over ons | Gezondheidsraad

3. JCVI (UK)

https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners
COVID-19: the green book, chapter 14a - GOV.UK (www.gov.uk)

4. NIAC (Ireland)

https://www.nitag-resource.org/sites/default/files/2023-05/20230411_NIAC_Recommendations_re._2023_COVID-19_Vaccination_.pdf
https://rcpi.access.preservica.com/uncategorized/IO_3537e4d8-e170-4922-b566-8cfc6b148ed2/

5. NACI (Canada)

https://www.nitag-resource.org/sites/default/files/2023-04/NACIstatement.pdf

6. ATAGI (Australia)

https://www.nitag-resource.org/sites/default/files/2023-02/ATAGI%202023%20booster%20advice%20.pdf

7. CDC (US)

Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals | CDC

8. STIKO (DE)

https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2023/21/Art_01.html
https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2023/Ausgaben/21_23.pdf?__blob=publicationFile

VI COMPOSITION OF THE WORKING GROUP

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

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

Based on the discussions and conclusions of the NITAG meeting on April 20 2023 and June 01 2023, this advisory report was drafted. The following experts participated at the NITAG meeting and approved the conclusions or send their approval by mail on 02 June 2023. The NITAG meeting was co-chaired by **David TUERLINCKX** and **Steven CALLENS.** The scientific secretariat was provided by Fabrice PETERS and Veerle MERTENS.

BEUTELS Philippe	Health economics	U Antwerpen
BLUMENTAL Sophie	Pediatric infectious disease	ULB - HUDERF
CALLENS Steven	Infectiology, internal medicine	UZ Gent
CARRILLO SANTISTEVE Paloma	General medicine, vaccinology and preventive medicine	ONE
CHATZIS Olga	Pediatrics, vaccinology and infectiology	UCL
DAELEMANS Siel	Pneumology, pediatrics and infectiology	UZ Brussel
DE SCHRYVER Antoon	Occupational and environmental medicine	U Antwerpen
DE SCHEERDER MarieAngélique	Internal medicine, infectiology, travel clinic and HIV	UZ Gent
DOGNE Jean Michel	Pharmacy and pharmacovigilance	U Namur, AFMPS, EMA
FRERE Julie	Pediatrics and infectiology	CHR Citadelle
GOETGHEBUER Tessa	Pediatrics	CHU St Pierre - ONE
GOVAERTS Frans	General medicine, prevention and health promotion	Domus Medica
MAERTENS Kirsten	Vaccinology and maternal immunization	U Antwerpen
MALFROOT Anne	Pediatrics and infectiology	UZ Brussel
MICHIELS Barbara	General medicine	U Antwerpen
PELEMAN Renaat	Infectiology and vaccinology	UZ Gent
ROBERFROID Dominique	Epidemiology, anthropology and health sciences	KCE, U Namur
ROSSI Camelia	Infectiology, HIV, travel and internal medicine	CHU Ambroise Paré
SCHELSTRAETE Petra	Pediatrics, pneumology and infectiology	UZ Gent
SPODEN Julie	General medicine	SSMG
SWENNEN Béatrice	Epidemiology and vaccinology	ULB

TILMANNE Anne	Medecine, pediatrics and infectiology	CHU Tivoli
TUERLINCKX David	Pediatrics and vaccinology	CHU UCL Namur
VAN DER LINDEN Dimitri	Pediatrics, infectiology, travel medicine and HIV	UCL
VAN LAETHEM Yves	Infectiology, vaccinology and travel medicine	ex-CHU Saint-Pierre, ULB
VEKEMAN Veerle	General medicine	Kind en Gezin
WAETERLOOS Geneviève	Quality of vaccines and blood products	Sciensano

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

DAEMS Joêl	Directorate Drugs	RIZIV - INAMI
JONG Veerle	Infection control and vaccinology	VAZG
LEROUX-ROELS Isabel	Vaccinology, infection prevention and microbiology	UZ Gent
MALI Stéphanie	Coordinator, center of excellence for vaccines	AFMPS - FAGG
THEETEN Heidi	Vaccinology	VAZG
TOP Geert	Manager vaccination program	VAZG
WUILLAUME Françoise	Vaccine vigilance	AFMPS - FAGG

About the Superior Health Council (SHC)

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

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

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

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

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

www.shc-belgium.be

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