



**Superior
Health Council**

VACCINATION AGAINST COVID-19 OF CHILDREN AGED 5-11 YEARS IN BELGIUM

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.be

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Federal Public Service Health, Food Chain Safety
and Environment

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ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL no. 9680

Vaccination against COVID-19 of children aged 5-11 years in Belgium

In this scientific advisory report, which offers guidance to public health policy-makers, the Belgian Superior Health Council provides recommendations of COVID-19 vaccination for children aged 5-11 years.

This report aims at providing to the Belgian Immunization Strategy and Operationalization Taskforce and general practitioners with specific recommendations on strategic COVID-19 vaccination in Belgium.

This urgent version was approved by the members of *ad hoc* working group – NITAG and the Board on 15 December 2021.

This version will be validated by the Committee on 5 January 2022¹.

I INTRODUCTION

On September 30 2021, the Superior Health Council (SHC) received a request for advice from the Task Force operationalisation vaccination strategy COVID-19 on the need to vaccinate children aged 5-11 years with Comirnaty® (mRNA vaccine from BioNTech/Pfizer) from a public health and individual point of view.

In May 2021, the SHC published the recommendations on vaccination against SARS-CoV 2 for children aged 12 and over (SHC 9655, 2021).

Although the primary vaccination coverage (1 dose J&J or 2 doses AstraZeneca, Pfizer or Moderna) against COVID-19 in Belgium is 76% (Dec 3, 2021), it is not homogeneously distributed within the population between age groups and regions.

Unvaccinated children currently remain at high risk for infection with the SARS-CoV-2 virus and can contribute to the spread in schools and within households and to vulnerable groups. On November 25 2021, EMA approved the use of the first vaccine for this age group: Comirnaty® (mRNA vaccine from BioNTech/Pfizer).

According to EMA, the benefits of Comirnaty® in children aged 5 to 11 years outweigh the risks, particularly in those with conditions that increase the risk of severe COVID-19.

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 RECOMMENDATIONS

At this moment, the SHC can summarise the arguments and available facts as the following:

- Comirnaty® is safe and effective against symptomatic COVID-19 for children aged 5 to 11, as shown in a phase 3 trial;
- Healthy children aged 5-11 years are at low risk of developing severe COVID-19, leading to hospital admission or death. In rare cases however SARS-CoV-2 infection can lead to MIS-C and sometimes ICU hospitalisation;
- Children with comorbidities have a 12 times higher odds of hospitalisation and 19 times higher odds of ICU admission;
- The most common side effects after vaccination in children aged 5 -11 years are similar to those in people aged 12 years and above. They include pain at the injection site, tiredness, headache, redness and swelling at the site of injection, muscle pain and chills. These effects are usually mild or moderate and improve within a few days of vaccination;
- Studies on rare secondary effects after vaccination in large populations are scarce. Data from countries where mass vaccination started (such as US and Israel) are constantly being evaluated. To date (08/12/2021), over 4 million doses have been administered;
- Whereas the direct health effect of vaccinating healthy children might be limited, a reduction of infections and transmission in society would benefit children as it would help to prevent school closures and periods of quarantine;
- Infected children can contribute to the spread in schools and within households and to vulnerable groups, therefore the society could benefit from vaccination against COVID-19 in this age group;
- Recent modelling data from the SIMID consortium shows that improving vaccination coverage to at least 90% in each age cohort for 18+ has similar potential on hospital and ICU admission compared to introducing widespread vaccination of children aged 5 to 11 years (80% coverage), however, adapted social contact behaviour and/or new virus variants and adapted vaccines could substantially impact this finding. A combination of measures is needed.
- Important knowledge gaps and uncertainties remain such as the safety data (e.g. myocarditis, pericarditis) in a larger group of children aged 5-11 years which are scarce at the moment; protection of vaccination against MIS-C; the impact of natural infection; vaccination and waning of vaccine effectiveness and the emergence of new variants of concern such as the Omicron variant on the impact of vaccination.

To help controlling the COVID-19 pandemic, a combination of actions and tools is required. The current COVID-19 vaccines are highly effective. However, no single vaccine protects 100%. Therefore, besides vaccination, the SHC strongly reminds on the importance of non-pharmaceutical interventions (NPI) such as maintaining hand hygiene, physical distancing, barrier measures and ventilation, including in public spaces with only vaccinated people.

Based on the arguments and facts mentioned above and the current large circulation of the SARS-CoV-2 virus, the Superior Health Council (SHC) recommends:

- 1. Reinforcement of primary vaccination for the general adult population, this remains priority in the fight against severe COVID-19 and must be continued to be strongly promoted;**
- 2. Rapid implementation of a booster dose for the groups previously determined;**
- 3. Vaccination against COVID-19 of children aged 5-11 years with comorbidities (priority 1-2-3, SHC9618, SHC9641) or in close contact with people at risk;**
- 4. Vaccination against COVID-19 should be offered to children without comorbidities aged 5-11 years and should be based on an individual and voluntary base of the child and his/her parents or legal representative.**

Vaccination schedule for children aged 5-11 years:

Vaccination against COVID-19 for Children aged 5-11 years		
Primary vaccination	Type of primary vaccine	Primary vaccination schedule
Comirnaty® (10 µg) (BioNTech/Pfizer)	mRNA	2 doses of Comirnaty® 3 weeks apart

The dose of Comirnaty® for 5-11 years old will be lower than that used in people aged 12 and above (10 µg compared with 30 µg).

Important notes:

1. Clear and adapted information on the expected personal and societal benefits of vaccinating young children should be offered to the child and his/her parents or legal representative before accepting the vaccine.
2. Access to areas of public life for children of 5-11 years should not be restricted depending on their vaccination status (e.g. no extension of the Covid Safe Ticket to this age group), as previously recommended by the SHC for children aged 12-15 years (SHC 9655).
3. Vaccination may be carried out simultaneously or at any interval, but it is important to emphasize that, when vaccinating children, priority is always given to vaccines from the basic vaccination schedule (SHC 9675).
4. The SHC recommends vaccination against COVID-19, regardless of history of COVID-19 infection, at least 14 days after recovery of symptomatic COVID-19, or at least 14 days after a positive Polymerase Chain Reaction (PCR) test for asymptomatic COVID-19 (SHC 9634).

This recommendation is based on the current knowledge and will be adapted based on new information from new variants (such as Omicron) and information from large scale vaccination data.

III METHODOLOGY

After analysing the request, the Board and Chair of the area Vaccination identified the necessary fields of expertise. An *ad hoc* working group was then set up which included experts in pediatrics, infectiology, epidemiology, vaccinology, biostatistics and general medicine.

2 ad hoc meetings were organised, on November 19 2021 and on December 3 2021. The Belgium's Advisory Committee on Bioethics was heard during the last meeting. 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 preprint studies, 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.

Once the advisory report was endorsed by the working group and by the standing working group Vaccination (NITAG), it was ultimately validated by the members of the Board of the SHC.

Keywords

Keywords	<i>Sleutelwoorden</i>	<i>Mots clés</i>	<i>Schlüsselwörter</i>
Coronavirus	Coronavirus	Coronavirus	Coronavirus
Covid-19	Covid-19	Covid-19	Covid-19
Vaccination	Vaccinatie	Vaccination	Impfung
Comorbidity	Comorbiditeit	Comorbidité	Komorbidität
Prevention	Preventie	Prévention	Prävention
Child	Kind	Enfant	Kind

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V ELABORATION AND ARGUMENTATION

List of abbreviations used

ASNM	Agence Nationale de Sécurité du Médicament et des Produits de santé - France
BVK-SBP	Belgian Society of Paediatrics
CDC	Centers for Disease Control and Prevention - USA
COVAX	COVID-19 Vaccines Global Access
COVID-19	Coronavirus disease 2019
CST	Covid Safe Ticket (Belgium)
CT	Computed Tomography
CI	Confidence Interval
ECDC	European Centre for Disease Prevention and Control
EMA	European Medicines Agency
EU / EEA	<i>European Union / European Economic Area</i>
FDA	Food and Drug Administration - USA
HAS	Haute Autorité de Santé - France
ICU	Intensive care unit
IDSA	Infectious Diseases Society of America
IgG	<i>Immunoglobulin G (antibody)</i>
IMC	Inter-ministerial Conference on Public Health - Belgium
IR / IRR	incidence rate / incidence rate ratio (in epidemiology)
ISAA	Integrated Situational Awareness and Analysis - EU
IV	intravenous (injection)
LARS	Leerlingen Activiteiten en Registratie Systeem - Belgium
MIS-C	Multisystem inflammatory syndrome in children
mRNA	Messenger ribonucleic acid
NACI	National Advisory Committee on Immunization - Canada
NICU	Neonatal Intensive Care Unit
NIH	National Institute of Health - UK
NITAG	National Immunization Technical Advisory Group (in WHO)
NPI	Non-Pharmaceutical Interventions
PCR	<i>Polymerase Chain Reaction</i>
PICU	Pediatric Intensive Care Unit
PIMS-TS	pediatric inflammatory multisystem syndrome, temporally associated with SARS-CoV-2
Rt	effective reproduction number
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SHC	Superior Health Council - Belgium
SIMID	Simulation Models for Infectious Diseases
STIKO	Ständige Impfkommision - Germany
VE-D	Vaccine effectiveness against death
VOC	Variant of concern
VRBPAC	Vaccines and Related Biological Products Advisory Committee (in FDA)
UK	<i>United Kingdom</i> (of Great Britain and Northern Ireland)
UNICEF	United Nations International Childrens Fund
US / USA	<i>United States of America</i>
WHO	<i>World Health Organization</i>

1 COVID-19 in children aged 5-11 years

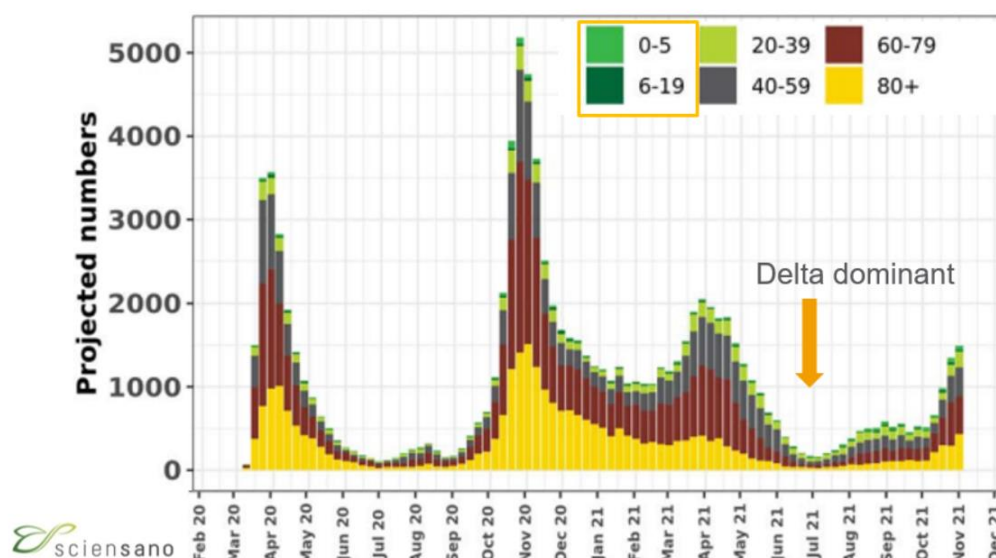
1.1 SARS-CoV-2 in children 5-11 years old: Belgian data

1.1.1 Severe disease in children (Sciensano)

In Belgium, detailed information on hospitalization is collected through the Sciensano Clinical Hospital Survey. The coverage of this survey is estimated at around 65% of all hospitalizations. We cannot estimate the coverage specifically for the pediatric population. Moreover, it is not always clear whether patients are admitted *because of* COVID-19 or *with* COVID-19 (incidental find upon screening when admitted for others reasons). Important to note is that the coverage for MIS-C will be lower than for acute cases of COVID-19. This is due to the fact that the Clinical Hospital Survey aims to capture acute cases of COVID-19 with a positive COVID-19 molecular test or typical imaging on CT Thorax. In contrast, MIS-C is a delayed presentation and SARS-CoV-2 PCR testing often yields a negative result.

Overall, the burden of severe disease in younger children is limited and **the age group only makes up a very small proportion of all hospitalizations for COVID-19**, as can be seen from Figure 1.

Figure 1: Numbers of hospitalizations due to acute COVID-19 by age group (corrected for coverage of 65%) for Belgium since the start of the pandemic. Source: Clinical Hospital Survey



Nevertheless, countries like the US have reported increasing in hospitalizations in children after the delta variant became dominant and in the context of rising case numbers in society overall. This phenomenon has not been observed in Belgium.

Since the start of the pandemic, 135 children aged 5-11 years have been hospitalized because of symptoms of COVID-19. An additional 192 children in this age group were hospitalized for other reasons and received a positive SARS-CoV-2 result upon screening. As hospitalization for these children is not a sign of severe disease of COVID-19 but an independent event, we exclude them from further analysis. Another 98 children were admitted to hospital with a positive COVID-19 test but without further information on reason of admission or reason of testing.

For children aged 5-11 years admitted to hospital because of COVID symptoms or for unknown reasons, the **median length of stay was 3 days (interquartile range 2-5)**. Fifteen percent of these children required intensive care. Half of the children in intensive care were reported to have MIS-C. Also, half of the children admitted to ICU had underlying comorbidities.

Fortunately, outcome for all these children was good. Mortality due to COVID-19 in children is very rare. Overall, <5 deaths in children and adolescents <18 years have been observed since the start of the pandemic, and zero deaths occurred in the age group 5-11 years.

1.1.2 Infection in children (Sciensano)

For the epidemiology in children, we have two important data sources: seroprevalence data and data on number of laboratory-confirmed cases.

The seroprevalence study repeatedly tests for antibodies in saliva samples of a representative sample of children and school staff. The full report is available here: https://www.sciensano.be/sites/default/files/report_seroprev_sars-cov-2_schools_t4_oct2021.pdf.

Over 1 out of 4 school children aged 7-9 years old already presented serological evidence of past infection at the sampling time point end of September (i.e. reflecting infections until ± Mid-September). In view of the recent rise in case numbers amongst this age group (see further) this is expected to still further increase.

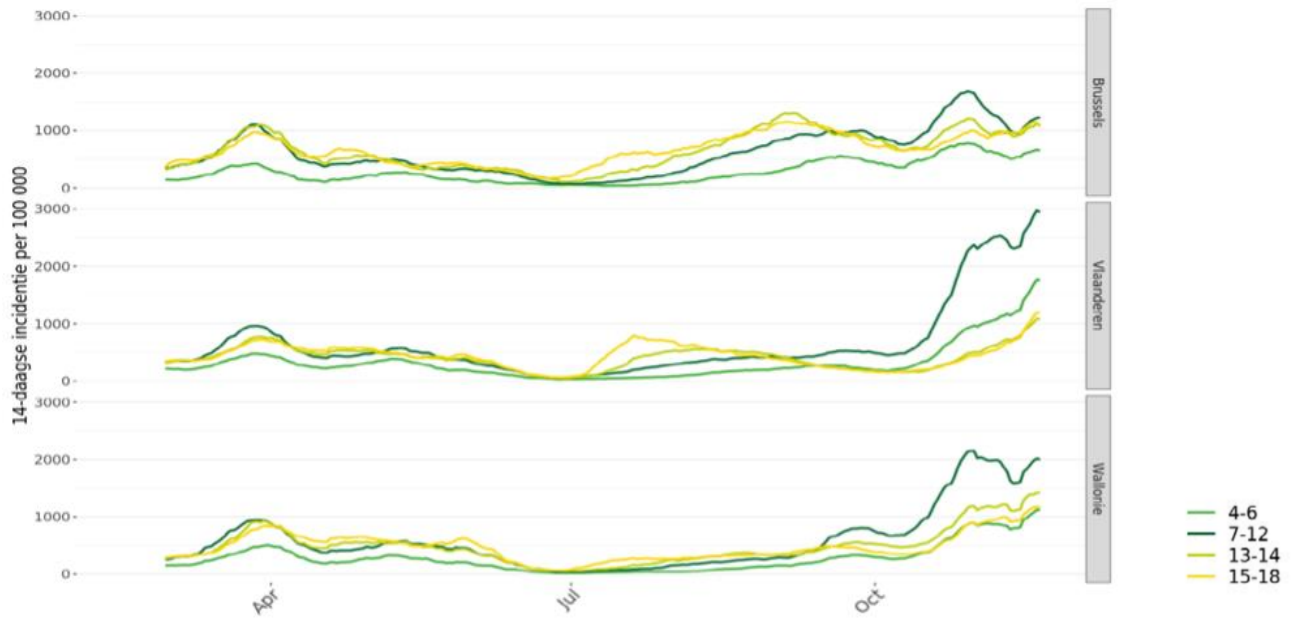
Table 3: Number and prevalence* of anti-SARS-CoV-2 antibodies (IgG) among primary (age 7-9) school pupils, Belgium and three regions, Sept 20th- Oct 8th 2021

	Number positive/total	Prevalence* % (95% CI)
Belgium	125/478	26.6 (21.5 – 32.8)
Brussels	23/62	36.1 (29.5 – 44.3)
Flanders	75/301	26.3 (19.3 – 35.7)
Wallonia	27/115	23.8 (17.6 – 32.0)

*adjusted for clustering of subjects within schools; CI, confidence interval

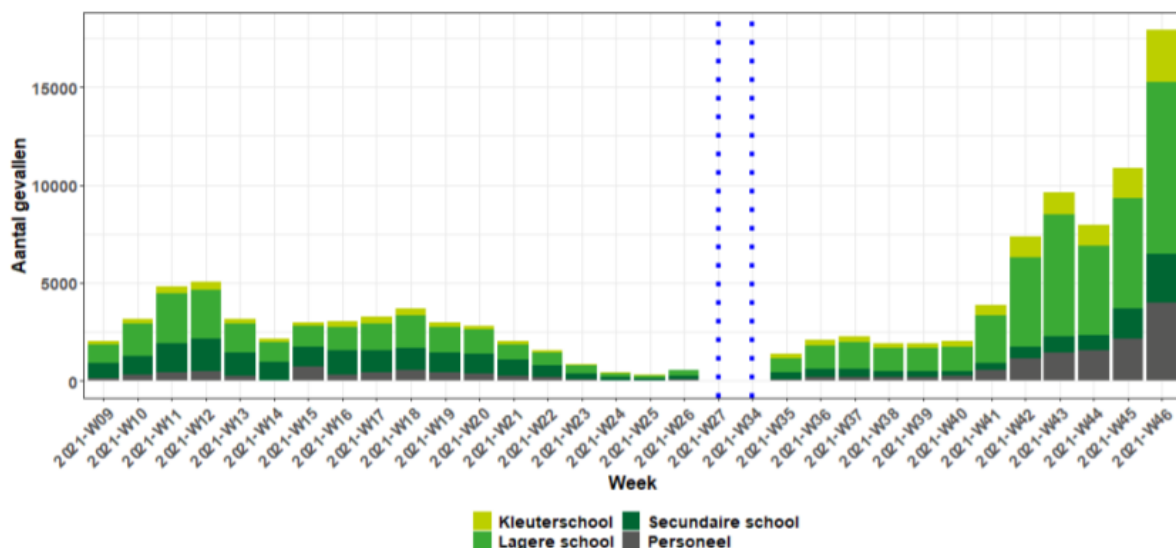
The second source of information is the number of laboratory-confirmed infections. Trends over time are not always easy to interpret, as the testing strategy has undergone numerous changes. For instance, reduced testing is in place since early November for high-risk contacts within the educational system. Nonetheless, where previously the incidence in adolescents was higher than in children in primary school, this has changed since the end of summer. We now observe very high incidences in children 7-12y of age.

Figure. 14-day cumulative incidence in children, by age group and region, 01/03-22/11/2021. Source: Sciensano COVID-19 laboratory surveillance



This clearly impacts the educational system. In week 46 (15-21/11/2021), >75% of schools in Flanders reported at least one active cluster. In contrast to last school year, cases are now predominantly reported from elementary and primary school. Whilst there might be a range of explanations for this observation (different behaviour, different contact tracing, more mask wearing), vaccination of pupils in secondary school likely also contributed.

Figure. Number of reported cases in schools in Flanders, by level of education, 1/03/2021 – 22/11/2021. Source: school surveillance LARS system department of education/Sciensano



1.1.3 *Belgian Survey 03-2020 to 02-2021 (BPS Congress, 03-2021)*

All Belgian pediatricians were invited to report data on hospitalized children (aged 0-18 years) with positive SARS-CoV-2 PCR and/or a MIS-C diagnosis, from March 1st 2020 until February 28th 2021. An online survey was completed by each hospital, collecting aggregate data on pediatric and PICU/NICU inpatients. Forty-three hospitals representing 61% of the Belgian pediatric beds, and including 9 of the 10 Belgian PICU centers, participated in the study. A total of 804 cases SARS-CoV-2 PCR positive were included, 504 were hospitalized because of SARS-CoV-2. Of those 22% were aged 6 to 12 years old. Among the 134 MIS-C cases, 35% were 6-12 years old. No death was reported in the age group 5-11 years old.

1.2 International publications and data

1.2.1 *Death from SARS-CoV-2 in children aged 5-11 years*

Different publications studied death related to SARS-CoV-2 in children 5-11 years old. In the UK, Smith et al. showed that 0,1 (0,0 – 0,3)/100 000 person-year die from SARS-CoV-2 infection in children 5-9y UK (Smith et al., 2021).

ECDC data reports 2 deaths in children 5-11 years old for the period in which the Delta VOC became and remained dominant (weeks 28 to 39 2021) among the 65 800 symptomatic cases aged 5-11 years that were notified during this period (ECDC, 2021).

1.2.2 *Hospitalisation and ICU because of SARS-CoV-2 in children aged 5-11 years*

For the period in which the Delta VOC became and remained dominant (weeks 28 to 39 2021), ECDC reports data of 65 800 symptomatic cases aged 5-11 years that were notified. 399 were hospitalised (risk: 0.61%; 95% CI: 0.55-0.67%) and 42 were severely hospitalised (ICU) (risk among all cases: 0.06% (95% CI: 0.05-0.09%); risk among hospitalised cases: 10.5% (95% CI: 7.7-14.0%) - ECDC, 2021).

According to multiple studies, 60-70% of ICU admission are linked to MIS-C (Belgian Survey SBP BVK 03-2021; Tagarro et al., 2021) and higher rate of MIS-C is found in the age group 6-12 years old compared to other age groups.

1.2.3 *Multisystem inflammatory syndrome in children (MIS-C)*

Multisystem inflammatory syndrome in children (MIS-C) is a condition where different body parts can become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs. The syndrome is rare and an increase in cases seem to occur weeks after the COVID-19 epidemic peak.

The estimated incidence is about 300 per 1,000,000 SARS-CoV2 infections (or about 1/3000) in children and adolescents < 21 years (US, CDC), which is comparable to the estimated incidence of 2-5 cases per 10000 SARS-CoV-2-infected children (Germany). The median age of reported cases is 8 years. In almost half of the cases (44.7%), MIS-C occurs in children aged 5-11 years.

MIS-C frequently leads to severe symptomatology, hospitalisation and admission to a paediatric intensive care unit (PICU). Despite the often severe initial course of the disease, recognition of the entity, multidisciplinary approach and prompt treatment with anti-inflammatory drugs and immune modulators (IV immunoglobulins, or corticotherapy or bioagents such as anakinra) usually lead to rapid clearance of symptoms. Prognosis is good with a reported mortality in large cohorts of 1-2%. Long-term follow-up is still under investigation; already available reports with follow-up of more than one year after MIS-C

occurrence show favourable results in terms of cardiac dysfunction (left ventricular dysfunction, coronary dilatation and arrhythmias), systemic inflammation and neurological outcome.

CDC shows a decrease in the ratio MIS-C cases on SARS-CoV-2 positive cases in the CDC data compared to last year (**CDC data** - [COVID Data Tracker Weekly Review | CDC](#)). There is no clear explanation to those numbers, and no data are available in Belgium for the time being.

1.2.4 Long-COVID in children aged 5-11 years

WHO published on October 6 2021 a clinical case definition based on the Delphi methodology ([A clinical case definition of post COVID-19 condition by a Delphi consensus, 6 October 2021 \(who.int\)](#)):

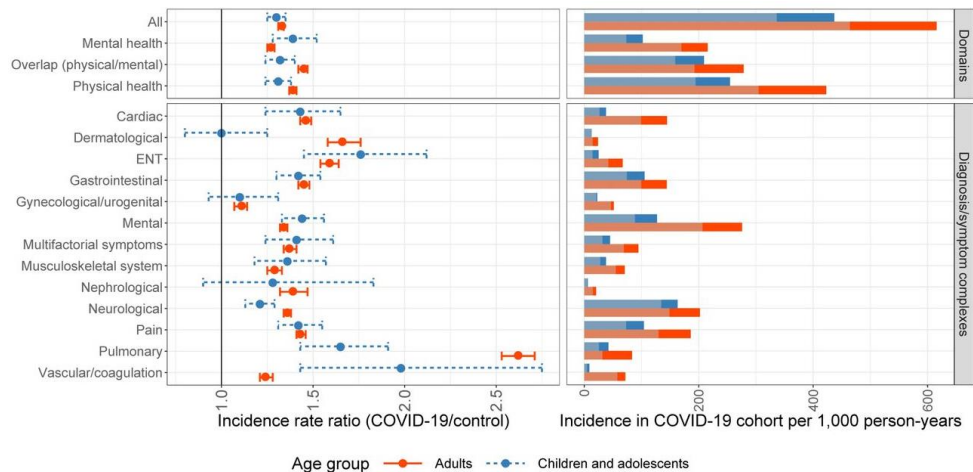
'Post COVID-19 condition occurs in individuals with a history of probable or confirmed SARS CoV-2 infection, usually 3 months from the onset of COVID-19 with symptoms and that last for at least 2 months and cannot be explained by an alternative diagnosis. Common symptoms include fatigue, shortness of breath, cognitive dysfunction but also others and generally have an impact on everyday functioning. Symptoms may be new onset following initial recovery from an acute COVID-19 episode or persist from the initial illness. Symptoms may also fluctuate or relapse over time.'

Long Covid-19 in children has been reported in cohorts of children. Symptoms did not persist longer than 12 weeks in most children. Of five studies that included a control group consisting of children and adolescents without SARS-CoV-2 infection, two did not find persistent symptoms to be more prevalent in children and adolescents with evidence of SARS-CoV-2 infection (Zimmermann et al., 2021).

The Clock Study in the UK by Stephenson et al. is a cohort in children aged 11-17 years so younger age groups are not included at this moment (Stephenson et al., 2021).

Roessler et al. included children (N= 31,345 between 0-11 years) and adults in a matched cohort study. The incidence rate of documented health problems in the COVID-19 cohort was significantly higher than that in the control cohort. Across all outcome domains and diagnosis/symptom complexes, incidence rates in the COVID-19 cohort were lower in children/adolescents than in adults (figure below).

The outcomes with the highest IRR in children and adolescents were **malaise/fatigue/exhaustion** (IRR=2.28, 95%-CI=[1.71-3.06], IR COVID-19=12.58, IR Control=5.51), **cough** (IRR=1.74, 95%-CI=[1.48-2.04], IR COVID-19=36.56, IR Control=21.06), and **throat/chest pain** (IRR=1.72, 95%-CI=[1.39-2.12], IR COVID-19=20.01, IR Control=11.66).



Healthy children between 5-11 years are at low risk of developing severe COVID-19, leading to hospital admission or death.

In rare cases however SARS-CoV-2 infection can lead to MIS-C and sometimes ICU hospitalisation.

Children could suffer from long-term sequelae after SARS-CoV-2 infection, but the exact burden is still to be determined and needs further research.

1.3 COVID-19 vaccine for children aged 5-11 years

1.3.1 Comirnaty® (Pfizer/BioNTech): effectiveness and immune response

At this moment, there is one vaccine available for this age group, Comirnaty®.

A study by Walter et al. in children aged 5 to 11 with a median follow-up of 2.3 months showed that the immune response to Comirnaty given at a lower dose (10 µg) in this age group was comparable to that seen with the higher dose (30 µg) in 16- to 25-year-olds (as measured by the level of antibodies against SARS-CoV-2). The efficacy of Comirnaty was calculated in almost 2,000 children from 5 to 11 years of age who had no sign of previous infection. These children received either the vaccine or a placebo (a dummy injection). Of the 1,305 children receiving the vaccine, three developed COVID-19 compared with 16 out of the 663 children who received placebo. This means that, in this study, the vaccine was **90.7% effective at preventing symptomatic COVID-19** (95% CI 67.7%, 98.3%).

They also measured the immune response for 2 doses of the Pfizer-BioNTech COVID-19 vaccine in children aged 5–11 years without evidence of previous SARS-CoV-2 infection. One month after the second dose, the geometric mean ratio of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) neutralizing titers in 5-to-11-year-olds to those in 16-to-25-year-olds was 1.04 (95% confidence interval [CI], 0.93 to 1.18), a ratio meeting the prespecified immunogenicity success criterion (lower bound of two-sided 95% CI, >0.67; geometric mean ratio point estimate, ≥0.8) (Walter et al., 2021).

There is no data about asymptomatic carriage of SARS-CoV-2 in this publication.

Comirnaty® is effective against symptomatic COVID-19 for children aged 5 to 11 and immunogenic, as shown in a phase 3 trial.

1.3.2 Safety of Comirnaty® vaccination in children 5-11 yrs

The safety profile of the vaccine in children is similar to that of adolescents according to Walter et al. The most common side effects being fever, injection-site pain, severe fatigue, headache, chills, and muscle pain. However, the study is too small and not powered to show rare side effects like myocarditis described in adolescents and young adults, mainly in young men after the second mRNA vaccine dose (Moderna > Pfizer) (Walter et al., 2021).

Large vaccination in this age group in countries like Israel, Canada and USA should provide reliable data in the following weeks. To date (dd 8/12/2021), millions of doses have been administered to children aged 5-11 years (<https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends>). Possible rare side effects (e.g. myocarditis) are constantly being monitored.

In Israel and the United States, the incidence of myocarditis in children 12 to 15 years of age receiving mRNA vaccines is less than in those receiving the vaccine in the 16- to 25-year-old age group.

Because the dose of Pfizer's mRNA is one-third of the dose given to older adolescents, myocarditis in the younger age group might be even more rare. But as the median age of MIS-C cases is 8 years, close follow up is warranted.

Comirnaty® is safe for children aged 5 to 11 years.

The most common side effects in children aged 5 to 11 are similar to those in people aged 12 and above. They include pain at the injection site, tiredness, headache, redness and swelling at the site of injection, muscle pain and chills. These effects are usually mild or moderate and improve within a few days of vaccination.

Possible rare side effects (e.g. myocarditis) are constantly being monitored.

1.4 Potential impact of vaccinating children between 5-11 years on transmission of SARS-CoV-2

Children can transmit SARS-CoV-2, in a proportion equal or smaller than adults according to studies, and they are more frequently asymptomatic than adults (Dawood et al., 2021; Lam-Hine et al., 2021).

However, the probability of adults and the elderly to contract the infection is decreasing throughout the vaccination campaign, thereby modifying the picture over time.

The dynamics of the epidemic with largely unvaccinated childhood age groups can gradually become more important drivers of SARS-CoV-2 transmission than predominantly vaccinated adult age groups.

ECDC presented an estimated relative reduction of the R_t in the population as a whole for the EU average and four hypothetical country settings with different vaccine uptakes in adults and children. For the EU average, they estimate that vaccinating children aged 5-11 years will decrease the R_t in the population as a whole by 10.9% (95% CI: 2.8-22.4%) (ECDC, Dec 1 2021).

Singanayagam et al., 2021 were not able to show an impact of vaccination on within-household transmission from symptomatic vaccinated and unvaccinated index cases in UK. However, they found a faster mean rate of viral load decline in fully vaccinated individuals with delta variant infection (0.95 log₁₀ copies per mL per day) than in unvaccinated individuals with pre-alpha (0.69), alpha (0.82), or delta (0.79) variant infections.

In a study among household close-contacts of all locally-acquired COVID-19 cases in Singapore (753 contacts), the secondary attack rate, regardless of symptoms, among unvaccinated Delta contacts was 25.8% (95% bootstrap confidence interval [BCI] 20.6–31.5%) compared to 11.3% (95%BCI 6.1–17.3%) among fully vaccinated Delta contacts. In this study, complete vaccination had a vaccine effectiveness of 56.4% (95%BCI 32.6–75.8%) against acquisition, 64.1% (95%BCI 37.8–85.4%) against symptomatic disease and 100% against severe disease among Delta contacts (Oon TN et al., t 2021).

Vaccination is highly efficient but not sufficient to prevent all transmission of the delta variant. Increasing population immunity via booster programs and vaccination of teenagers will help to increase the effect of vaccination on transmission. Direct protection of individuals at risk of severe outcomes, via vaccination and non-pharmacological interventions, will remain central to containing the burden of disease caused by the delta variant.

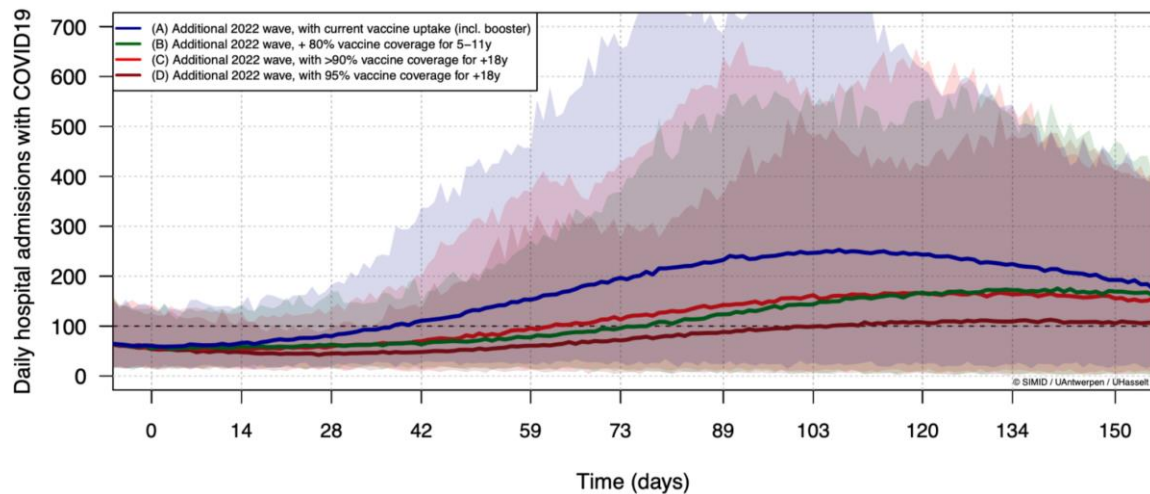
1.5 Model simulations on childhood and adult vaccination (by the SIMID consortium)

The aim of this paragraph is to investigate the potential effects of vaccination of 5-11-year-olds. It contains what-if scenarios, which are not intended as predictions to compare with (updated) reported burden of disease evolutions. Current data on the Omicron VOC is insufficient to inform these model scenarios. Therefore the Delta VOC remains the dominant strain in these simulations. We do explore a resurgence of COVID-19 in the first quarter of 2022 due to increased transmission, without defining the specific cause, but under the assumption that vaccines continue to protect at currently observed levels (i.e. implicitly accounting for the currently still dominating delta variant).

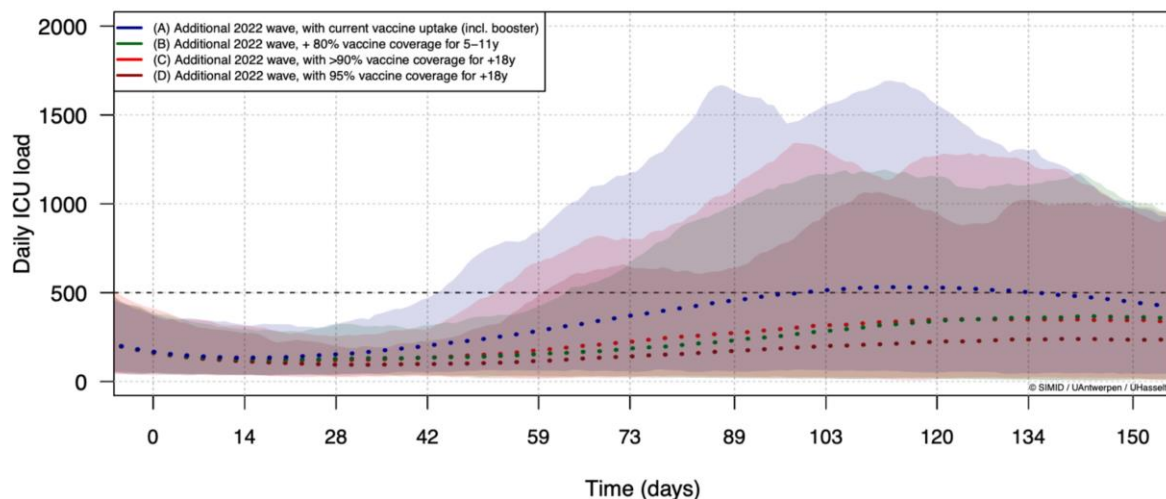
A stochastic transmission model of the SIMID consortium applied to Belgium (Abrams et al., 2021), recalibrated on 7th December 2021 using empirical social contact data up to end November 2021 from the Comix study (Verelst et al., 2021; Coletti et al., 2021) shows that vaccination of children aged 5 to 11 years can have an important impact COVID-19 waves of infections, hospital admissions and ICU load, by substantially delaying the rise of such waves, and flattening their peak (see separate technical note SIMID consortium, 2021).

This is demonstrated for (1) future scenarios, given a fifth wave in the first quarter of 2022 (by reapplying and maintaining transmission dynamics observed in October 2021, at both 100% (main text of technical note) and 120% (Addendum to technical note, SIMID consortium, 2021, see figure below), and (2) a counterfactual scenario for vaccination in the past, i.e., assuming that we vaccinated (a large fraction of all) children between 5 and 11 years old prior to the fourth wave in Belgium (i.e., vaccination starting in July 2021).

Figure 1: Comparative impact on a hypothetical future wave of introducing universal childhood vaccination at 80% coverage OR increasing vaccination coverage to at least 90% at any adult age



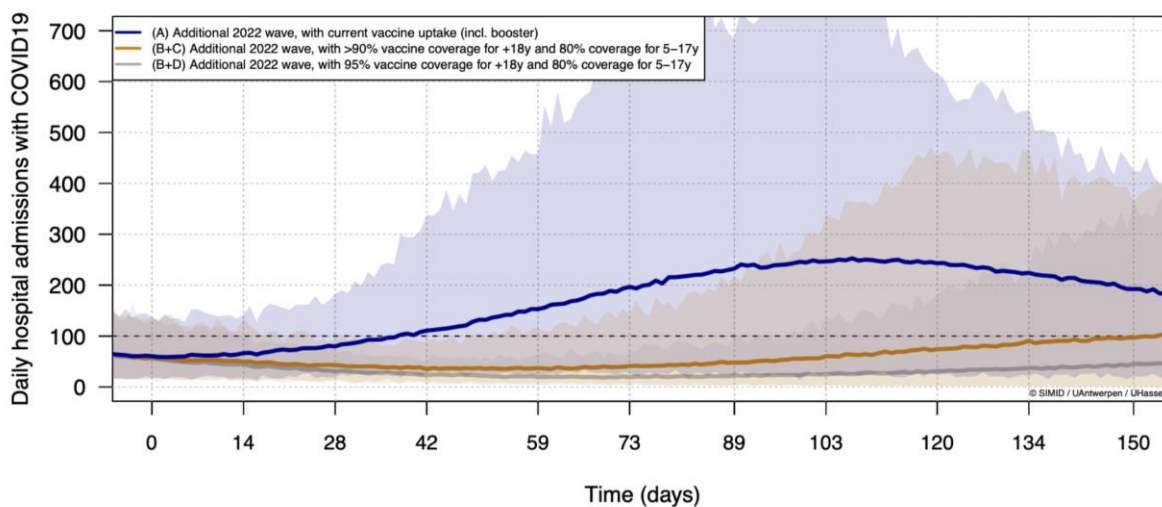
(a) Daily hospital admissions with COVID-19



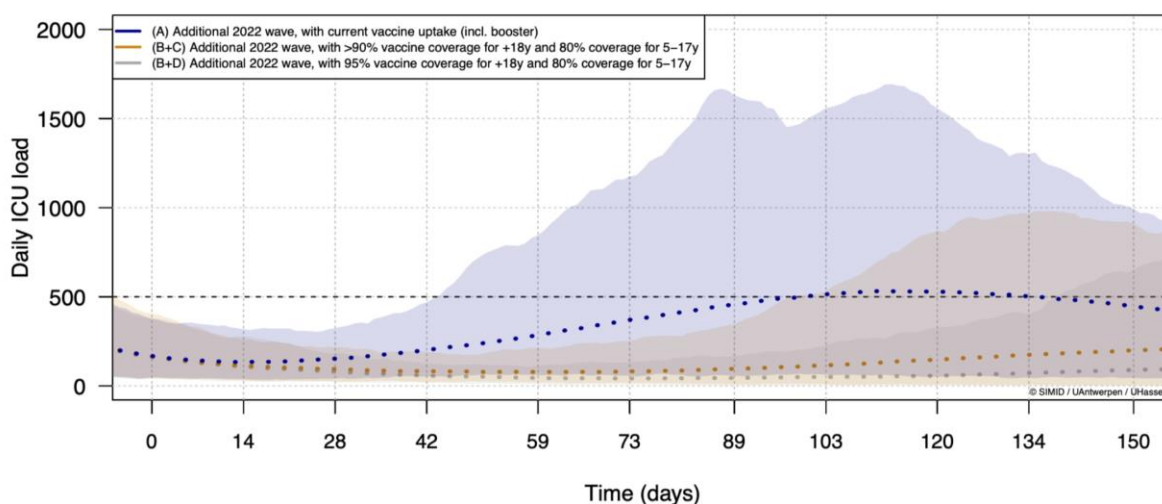
(b) ICU occupancy

The added benefit of vaccine uptake in young children is mainly a consequence of its capacity to reduce transmission to and therefore between older age groups in the community. For a hypothetical wave in 2022, with specified risk behaviour, VOC and vaccine assumptions in place (see technical note SIMID consortium), improving vaccination coverage to at least 90% in each age cohort for 18+ has similar potential compared to introducing widespread vaccination of children aged 5 to 11 years, though adapted social contact behaviour and/or new virus variants and adapted vaccines could substantially impact this finding. Simulations with vaccination coverage of 95% in the complete Belgian population over the age of 18 years would prevent at least 30% of hospitalizations (see figure 1). A combined strategy, through which both universal vaccination of children is introduced and vaccine uptake in adults is increased has substantial added benefit relative to either strategy on its own (compare figure 2 to figure 1). Furthermore, such a combined strategy is likely to reduce uncertainty related to modified transmission dynamics associated with the rise of a new VOC.

Figure 2: Comparative impact on a hypothetical future wave of introducing universal childhood vaccination at 80% coverage AND increasing vaccination coverage to at least 90% at any adult age



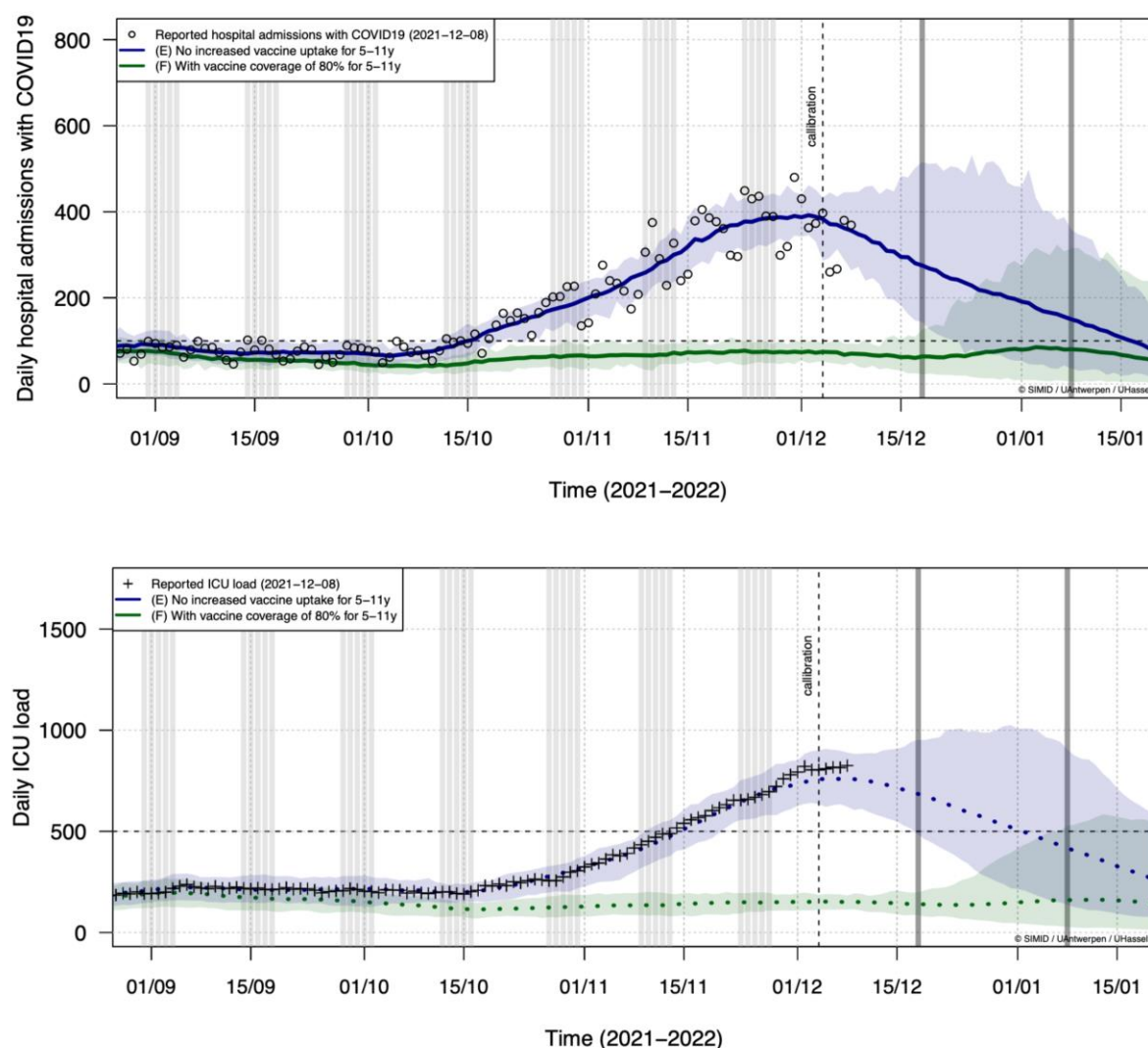
(a) Daily hospital admissions with COVID-19



(b) ICU occupancy

The retrospective counterfactual analysis, in which children between 5 and 11 years old would have been vaccinated in July and August 2021, shows a manageable constant level of hospital admissions and ICU load from September until December 2021 (see figure 3).

Figure 3: Retrospective analysis of the fourth wave in Belgium without universal vaccination of 5-11 year olds (factual scenario up to the present time) and with vaccination of 5-11 year olds at 80% coverage (a counterfactual scenario). Top panel: hospital admissions, bottom panel: ICU load.



Two important counterbalancing limitations have to be borne in mind when interpreting these results: (1) these simulations explicitly account for waning vaccine-induced immunity (as a function of time since the last dose, including booster doses), but not for waning immunity of persons previously infected by the virus. Clearly, this implies that the potential impact of vaccinating children is underestimated in this respect, as young children are not universally vaccinated but have often acquired infection (and here it is assumed that infection-induced immunity does not wane) ; (2) if the omicron VOC evades vaccine induced protection against infection more than against (severe) disease, the potential impact of childhood vaccination may be overestimated in this respect relative to the impact of adult vaccination. This second aspect is currently unknown.

1.6 Risks and benefits of vaccinating children aged 5-11 years

FDA conducted a quantitative benefit-risk analysis to evaluate predicted numbers of symptomatic COVID-19 cases, hospitalizations, ICU admissions, and deaths that would be prevented per million fully vaccinated children 5-11 years of age over a 6-month period, as compared with predicted numbers of vaccine-associated excess myocarditis cases, hospitalizations, ICU admissions and deaths per million fully vaccinated children 5-11 years of age. The model conservatively assumed that the risk of myocarditis/pericarditis associated with the 10 µg dose in children 5-11 years of age would be the same as the estimated risk associated with the 30 µg dose in adolescents 12-15 years of age from Optum healthcare claims data. While benefits of vaccination were highly dependent on COVID-19 incidence, the overall analysis predicted that the numbers of clinically significant COVID-19-related outcomes prevented would clearly outweigh the numbers of vaccine-associated excess myocarditis cases over a range of assumptions for COVID-19 incidence. At the lowest evaluated COVID-19 incidence (corresponding to the June 2021 nadir), the predicted number of vaccine-associated myocarditis cases was greater than the predicted number of COVID-19 hospitalizations prevented for males and for both sexes combined. However, in consideration of the different clinical implications of hospitalization for COVID-19 versus hospitalization for vaccine associated myocarditis, and benefits related to prevention of non-hospitalized cases of COVID-19 with significant morbidity, **the overall benefits of the vaccine may still outweigh the risks under this low incidence scenario**. If the myocarditis/pericarditis risk in this age group is lower than the conservative assumption used in the model, the benefit-risk balance would be even more favorable (VRBPAC meeting October 26 2021, <https://www.fda.gov/media/153447/download>).

According to FDA, 62 PICU admissions will be avoided for 1 million of children aged 5-11 years fully vaccinated (Peter Marks FDA, CDC-IDSA webinar 6-11-2021). **However, PICU admission rate is higher in US (30%; Preston et al., 2021) than European countries (8%-18%; Götzinger et al, 2020; Swann et al., 2020; Tagarro et al., 2021; Belgian Survey SBP BVK 03-2021).**

The **potential objectives for vaccinating children aged 5-11 years** are summarized in the recently published ECDC report ([ECDC, Dec 2021, pg 14](#)):

- a) Protecting children from the direct health risks of COVID-19
The primary objective of vaccinating children is the protection of their individual health against COVID-19. It is clear from the data presented that not all children in this age group have the same risk of developing severe COVID-19 or experiencing its sequelae (e.g. post COVID-19 condition). Children at high medical risk of severe COVID-19 (i.e. those with underlying conditions that increase the risk of severe COVID-19) would particularly benefit from vaccination and should be prioritized once the vaccine is authorized in their age group. Other children, such as those belonging to socially vulnerable groups, could also be more frequently exposed to SARS-CoV-2 and to the risk of more severe health outcomes.
- b) Protecting children from the indirect impacts of the COVID-19 pandemic
The formative years of early childhood are crucial to future health and well-being, during which children experience rapid cognitive, social, emotional, and physical development. The COVID-19 pandemic restrictions have had a strong negative impact on children and their families. Significant negative effects on the physical and mental health, as well as the overall well-being, of children have been documented. Vaccinating children could offer them increased opportunities to more safely spend time with friends and extended family, resume social and extracurricular activities, and socialise safely.

The negative impact of school disruption has been substantial during the COVID-19 pandemic, including direct loss of learning, reduced educational performance, and increased risk of disengagement and school dropout. For vulnerable or at-risk children, including those with medical vulnerabilities or special education needs, vaccination could help to ensure their safe access to education. With continued community transmission, vaccination of children more generally could significantly prevent repetitive learning disruptions due to isolation and quarantine practices after exposure to a confirmed case.

Furthermore, vaccination could allow for the relaxation of in-school protection measures and non-pharmaceutical interventions, such as the use of masks and physical distancing, which may in some contexts be disruptive to normal school life.”

c) Reducing the overall burden of COVID-19 among children

As the Delta VOC is highly transmissible, a large number of infections could rapidly occur among unvaccinated populations with frequent social interactions. Despite the low individual risk of developing severe COVID-19 faced by healthy children aged 5-11 years, a very high number of infections in this age group could nonetheless lead to a large absolute number of severe cases over a limited time period. Non-pharmaceutical measures, such as physical distancing or the wearing of face masks, are helpful in reducing SARS-CoV-2 transmission. However, it may be challenging to implement these measures in this age group, perhaps particularly outside of controlled settings (e.g. school) and over a long period of time.

Vaccination against COVID-19 could therefore be helpful in reducing the overall burden of COVID-19 among children aged 5-11 years, given a favourable individual benefit-risk profile and sufficient and lasting protection against SARS-CoV-2 transmission, which could reduce the need for strict non-pharmaceutical measures.

d) Reducing SARS-CoV-2 circulation in the overall population

The overall circulation of SARS-CoV-2 may remain moderate-to-high if some age groups with a lot of contacts (e.g. children) are largely unvaccinated. In countries where transmission rates remain high, this could also have important public health consequences with regard to the frequency of severe disease and the pressure on healthcare.

According to the modelling analysis, vaccinating children—particularly in contexts where vaccine uptake in adults has already reached a high coverage level – could significantly contribute to reducing the overall viral circulation in the population and potential increases in the number of severe cases and hospitalisations. This will strongly depend on how much the vaccination of children reduces SARS-CoV-2 transmission and on the duration of such protection.

Important knowledge gaps and uncertainties remain such as the safety data (e.g. myocarditis, pericarditis) in a larger group of children aged 5-11 years which are scarce at the moment; protection of vaccination against MIS-C; the impact of natural infection; vaccination and waning of vaccine effectiveness and the emergence of new variants of concern such as the Omicron variant on the impact of vaccination.

2 Position EMA

On November 25, 2021, EMA's human medicines committee (CHMP) has recommended granting an extension of indication for the COVID-19 vaccine Comirnaty to include use in children aged 5 to 11: [Comirnaty COVID-19 vaccine: EMA recommends approval for children aged 5 to 11 | European Medicines Agency \(europa.eu\)](https://www.europa.europa.eu/press-communications/infobox/infobox_12312_en.htm)

In children from 5 to 11 years of age, the dose of Comirnaty will be lower than that used in people aged 12 and above (10 µg compared with 30 µg). As in the older age group, it is given as two injections in the muscles of the upper arm, three weeks apart.

A main study in children aged 5 to 11 showed that the immune response to Comirnaty given at a lower dose (10 µg) in this age group was comparable to that seen with the higher dose (30 µg) in 16- to 25-year-olds (as measured by the level of antibodies against SARS-CoV-2). The efficacy of Comirnaty was calculated in almost 2,000 children from 5 to 11 years of age who had no sign of previous infection. These children received either the vaccine or a placebo (a dummy injection). Of the 1,305 children receiving the vaccine, three developed COVID-19 compared with 16 out of the 663 children who received placebo. This means that, in this study, the vaccine was 90.7% effective at preventing symptomatic COVID-19 (although the true rate could be between 67.7% and 98.3%).

The most common side effects in children aged 5 to 11 are similar to those in people aged 12 and above. They include pain at the injection site, tiredness, headache, redness and swelling at the site of injection, muscle pain and chills. These effects are usually mild or moderate and improve within a few days of vaccination.

The CHMP therefore concluded that the benefits of Comirnaty in children aged 5 to 11 outweigh the risks, particularly in those with conditions that increase the risk of severe COVID-19.

The safety and efficacy of the vaccine in both children and adults will continue to be monitored closely as it is used in vaccination campaigns in EU Member States through the EU pharmacovigilance system and ongoing and additional studies conducted by the company and by European authorities.

3 Position WHO

On November 24 2021, WHO published their Interim statement on COVID-19 vaccination for children and adolescents: [Interim statement on COVID-19 vaccination for children and adolescents \(who.int\)](https://www.who.int/news/item/24-11-2021-interim-statement-on-covid-19-vaccination-for-children-and-adolescents)

Conclusion:

Countries should consider the individual and population benefits of immunizing children and adolescents in their specific epidemiological and social context when developing their COVID-19 immunization policies and programs. As children and adolescents tend to have milder disease compared to adults, unless they are in a group at higher risk of severe COVID-19, it is less urgent to vaccinate them than older people, those with chronic health conditions and health workers.

There are benefits of vaccinating children and adolescents that go beyond the direct health benefits. Vaccination that decreases COVID transmission in this age group may reduce transmission from children and adolescents to older adults, and may help reduce the need for mitigation measures in schools. Minimizing disruptions to education for children and maintenance of their overall well-being, health and safety are important considerations.

Countries' strategies related to COVID-19 control should facilitate children's participation in education and other aspects of social life, and minimize school closures, even without vaccinating children and adolescents. UNICEF and WHO have developed guidance on how to minimize transmission in schools and keep schools open, regardless of vaccination of school-aged children.

Aligned and coordinated action is needed to achieve the global COVID-19 vaccination targets. Given current global inequity in vaccine access, the decision to vaccinate adolescents and children must account for prioritization to fully protect the highest risk subgroups through primary vaccination series, and as vaccine effectiveness declines with time since vaccination, through booster doses. As such, before considering implementing primary vaccination series in adolescents and children, attaining high coverage of primary series - and booster doses as needed based on evidence of waning and optimizing vaccination impact - in highest risk subgroups, such as older adults, must be considered.

As a matter of global equity, as long as many parts of the world are facing extreme vaccine shortages, countries that have achieved high vaccine coverage in their high-risk populations should prioritize global sharing of COVID-19 vaccines through the COVAX facility before proceeding to vaccination of children and adolescents who are at low risk for severe disease.

It is of utmost importance for children to continue to receive the recommended childhood vaccines for other infectious diseases.

4 Position ECDC

On December 1 2021, ECDC published '**Interim public health considerations for COVID-19 vaccination of children aged 5-11 years**':

[Interim public health considerations for COVID-19 vaccination of children aged 5-11 years \(europa.eu\)](https://ecdc.europa.eu/en/interim-guidance/covid-19/vaccination/children-5-11-years)

Key messages:

- *Surveillance data show that children aged 5-11 years have made up an increasing proportion of both notified cases and hospitalizations in EU/EEA countries in recent months. Although hospitalizations have increased in line with case rates in all age groups in the EU/EEA, disease severity of COVID-19 in children is generally mild with a favourable clinical outcome. Severe COVID-19 remains rare among children (of 65 800 notified symptomatic COVID-19 cases in children aged 5-11 years, reported from 10 EU/EEA countries during the period of B.1.617.2 (Delta) variant of concern (VOC) dominance, 0.61% were hospitalized and 0.06% needed intensive care unit (ICU)/respiratory support).*
- *The relative contribution of children to overall SARS-CoV-2 circulation may have increased due to factors including the emergence of the highly transmissible Delta VOC and increased vaccination coverage in older age groups.*
- *The presence of an underlying condition among children aged 5-11 years is associated with about 12 times higher odds of hospitalization and 19 times higher odds of ICU admission. However, the majority (78%) of hospitalized children of this age had no reported underlying medical condition.*
- *Paediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-2 / multi-inflammatory syndrome in children (PIMS-TS/MIS-C) and post COVID-19 condition have been reported in children aged 5-11 years, although it is difficult to quantify the prevalence and burden of these conditions. In a United States (US) Centers for Disease Control and Prevention (CDC) report, myocarditis was reported up to 37 times more often in unvaccinated children less than 16 years old with a COVID-19 diagnosis compared to other patients from the same age group.*

- *Beyond the direct health impacts of COVID-19 disease, the COVID-19 pandemic has affected the physical and mental health and well-being of children aged 5-11 years. Numerous factors, such as disruptions to important everyday social and educational activities, have caused anxiety and distress in this age group.*
- *Modelling data indicate that vaccinating children aged 5-11 years could reduce SARS-CoV-2 transmission in the whole population, although the extent and duration of this protection is currently unknown. It is estimated that the impact on the effective reproduction number (R_t) in the population as a whole would be a decrease of 11% (range: 8-15%, depending on vaccine uptake parameters of 30-70%) for an average country in the EU/EEA. This is comparable to the effect of some non-pharmaceutical interventions. The impact of vaccinating children is weaker for countries with a low adult vaccine uptake and stronger for countries with high uptake among adults.*
- *On 25 November 2021, the European Medicines Agency (EMA) granted a positive opinion for use of the Comirnaty COVID-19 vaccine in children aged 5-11 years based on a placebo-controlled randomized clinical trial in which more than 3 000 children in this age group received this vaccine.*

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VII 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](#)).

An ad hoc meeting was organised on Friday November 19 2021 and Friday December 3 2021. The following experts participated at the ad hoc meeting(s) and/or approval of the report by mail. The ad hoc working group was chaired by **Anne TILMANNE and Petra SCHELSTRAETE**; the scientific secretariat were Veerle MERTENS, Fabrice PETERS, Muriel BALTES and Jean-Jacques DUBOIS.

BEUTELS Philippe	Health Economics	UAntwerpen
BLUMENTAL Sophie	Pediatric Infectious Disease	HUDERF
BOIY Tine	Pediatrics	UZA
CALLENS Steven	Infectiology, Internal medicine	UZ Gent
CARILLO SANTISTEVE Paloma	General medicine, vaccination	ONE
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CORNELISSEN Laura	Epidemiology, Obstetrics, Gynaecology	Sciensano
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GOVAERTS Frans	General medicine	Domus Medica
HENS Niel	Biostatistics	UAntwerpen
MALFROOT Anne	Pediatrics, Infectiology	UZ Brussel
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SMEESTERS Pierre	Pediatrics	HUDERF
SPODEN Julie	General medicine	SSMG
SWENNEN Béatrice	Epidemiology, Vaccinology	ULB
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Bioethics
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Bioethics

VIII FAQ : VACCIN CONTRE LA MALADIE COVID-19 CHEZ LES ENFANTS DE 5-11 ANS

	Observé dans de larges populations de millions d'enfants de 5-11 ans vaccinés	Observé dans le cadre d'études scientifiques (souvent quelques milliers de patients)	Effet attendu, selon les avis des experts, mais non (encore) observé par des études	Pas d'information
Le vaccin protège-t-il contre la maladie Covid-19 et ses formes sévères, rares chez l'enfant ?	Plus de 4 millions d'enfants vaccinés à travers le monde (USA, Israël, Canada, ...), nous attendons la publication des données de surveillance.	Oui (efficacité du vaccin à 91%)	Oui Puisque ceci a été observé chez les classes d'âge plus avancées.	
Le vaccin protège-t-il contre le « PIMS » ou « MIS-C », la maladie inflammatoire qui peut survenir chez l'enfant quelques semaines après un Covid ?			Il existe probablement un effet protecteur contre le « PIMS » ou « MIS-C », mais les données sont manquantes pour en être certains.	
Le vaccin protège-t-il contre le « Covid-long » ?				Il manque actuellement de données claires sur le « Covid long » chez l'enfant. Il n'existe pas encore de données sur l'impact du vaccin sur celui-ci.

	Observé dans de larges populations de millions d'enfants de 5-11 ans vaccinés	Observé dans le cadre d'études scientifiques (souvent quelques milliers de patients)	Effet attendu, selon les avis des experts, mais non (encore) observé par des études	Pas d'information
Les effets secondaires <u>fréquents</u> du vaccin chez l'enfant de 5-11 ans sont-ils semblables à ceux observés chez les adolescents ?		Oui Par rapport aux adolescents : * plus de réactions locales (rougeur et douleur au site d'injection chez 1/10 vaccinés) * moins de réactions systémiques (fièvre 2-6/100, céphalées 1/5 à 1/3, fatigue 1/2)		
Les effets secondaires <u>rare</u> s du vaccin chez l'enfant de 5-11 ans sont-ils identiques à ceux observés chez les adolescents ?	? Plus de 4 millions d'enfants vaccinés à travers le monde (USA, Israël, Canada,...), nous attendons la publication des données de surveillance.		On s'attend à ce qu'ils soient les mêmes que ceux des adolescents, et probablement plus rares puisqu'une dose plus faible (1/3) de vaccin est utilisée chez les plus jeunes.	
Le vaccin empêche-t-il d'être porteur du virus ?	Non La vaccination n'empêche pas le portage, mais elle en diminue le risque. Ceci se voit très bien à l'échelle de populations vaccinées. L'importance de cette diminution de la transmission varie selon le contexte (types de contacts, variants circulants, ...).			

	Observé dans de larges populations de millions d'enfants de 5-11 ans vaccinés	Observé dans le cadre d'études scientifiques (souvent quelques milliers de patients)	Effet attendu, selon les avis des experts, mais non (encore) observé par des études	Pas d'information
La vaccination diminue-t-elle la transmission du virus SARS-CoV-2 ?	Oui, mais A l'échelle de larges populations cet effet est prouvé. A l'échelle de plus petites études, étudiant des transmissions dans des familles par exemple, cette diminution de la transmission n'est pas toujours visible car son effet varie selon le contexte (type de contact, variants circulants, ...).			
Le vaccin sera-t-il toujours efficace sur les variants du virus à venir ?				X Pas d'information pour le moment, notamment pour Omicron.
Quelle est la durée de protection offerte par le vaccin chez l'enfant, y aura-t-il une nécessité de rappel ?			La protection sera sans doute d'une durée similaire à celle observée chez les plus âgés (environ 6 mois). La nécessité de rappel est probable mais pas encore certaine.	

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