

COVID-19 vaccination of children aged 5 to 11

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Executive summary

Health Council of the Netherlands



The European Medicines Agency (EMA) recently recommended approval of the BioNTech/Pfizer vaccine against COVID-19 for use in children aged 5 to 11. The vaccine dose will be lower than that used in people aged 12 and above (10 micrograms per dose). The Minister of Health, Welfare and Sport asked the Health Council of the Netherlands to advise on which groups of children under 12 years of age would be recommended the vaccine. On 3 December 2021, the Health Council issued an advisory report to the Minister in which it recommended that the BioNTech/Pfizer vaccine be offered to children aged 5-11 with an underlying condition that increases the risk of developing severe COVID-19. In this advisory report, the Subcommittee on COVID-19 Vaccinations has assessed the issue of making the BioNTech/Pfizer vaccine available to children aged 5-11 who do not belong to medical risk groups. The Committee performed this assessment on the

basis of the fixed criteria used by the Health Council in its advice on vaccinations.

Risk of severe disease for small group of children

In most children, SARS-CoV-2 only causes very mild symptoms. A small group of children develops severe disease symptoms from COVID-19 requiring hospitalisation. In addition, in a number of children SARS-CoV-2 infection may result in MIS-C, a very serious condition where different body parts can become inflamed. MIS-C is a rare but potentially life-threatening complication arising from SARS-CoV-2 infection that may require children to be admitted to intensive care. Without vaccination, it is estimated that around 100 to 150 children will develop this condition. Furthermore, due to high virus circulation and preventive measures, COVID-19 has an indirect negative impact on children's health: limited

access to school, sports and social contact with peers, for example, can lead to poorer health outcomes and social-emotional development as well as learning disadvantages.

The vaccine is sufficiently effective

The BioNTech/Pfizer COVID-19 vaccine showed 90.7% efficacy in a clinical trial involving more than 2,200 children aged 5 to 11. The immune response was comparable to that observed in adolescents and young adults. It is expected, therefore, that the vaccine offers good protection against COVID-19 for children in the 5-11 age group.

The vaccine is sufficiently safe

Like all medicines, the BioNTech/Pfizer vaccine has side effects. The most common side effects in the 5-11 age group are pain at the site of injection, fatigue and headache. Side effects are more frequently observed following the second



dose and disappear after one to two days. Despite the lack of data from large observational studies, it is expected that any rare side effects will be limited in this age group. In very rare cases, myocarditis (inflammation of the heart muscle) may develop after vaccination; the Committee took this into consideration in its assessment.

The benefits of vaccination outweigh the potential harms and burdens

Article 3 of the International Convention on the Rights of the Child states that in all actions concerning children – in this case decisions on vaccination programmes for children – the best interests of the child shall be a primary consideration. According to the Committee, this means that vaccinating children for the sole purpose of reducing virus transmission in the population is unjustifiable. The Committee believes it is the responsibility of the government to protect the best interests of children by ensuring that vaccination always entails a certain degree of health benefits, either directly

or indirectly, for children themselves. Taking all considerations into account, the Committee is of the opinion that the benefits of vaccination for children aged 5-11 sufficiently outweigh the potential harms and burdens. A small number of children will experience complications in the form of MIS-C and/or severe COVID-19 and it is likely that vaccination can largely prevent this. Moreover, vaccination can reduce the indirect adverse health effects of the pandemic on children. It reduces the likelihood that, due to high virus circulation, restrictions will be needed which have a negative impact on children, including restricted access to school, sports and social contact with peers. In the Committee's opinion, these health benefits outweigh a relatively limited burden of vaccination, in the form of side effects most of which are mild and short term.

Recommendation

Everything considered, the Committee concludes on the basis of the currently available evidence that COVID-19 leads to a certain

degree of direct and indirect burden of disease among children aged 5-11. The Committee also finds that vaccination of this group with the adjusted children's dose of the BioNTech/Pfizer vaccine is sufficiently effective, sufficiently safe and acceptable. The Committee therefore recommends making the BioNTech/Pfizer vaccine available to (parents of) children aged 5-11 who wish to get vaccinated.

The Committee's recommendation is the result of a weighted appreciation of various factors. The main argument in support of making the vaccine available is that the Committee considers it likely that vaccination will prevent a small group of children from developing MIS-C and severe COVID-19. As all children aged 5-11 will at some point be exposed to SARS-CoV-2 without vaccination, the overall burden of disease is not insignificant (and includes an estimated 100 to 150 cases of MIS-C).

In addition, in the Committee gave weight to the indirect health benefits that children obtain from



vaccination, and their interests that may be served by making the vaccine available.

That vaccinating children also entails certain health benefits for the population as a whole is, in the Committee's view, an additional benefit which was taken into consideration but did not play a key role in its assessment. It should be noted also that making the vaccine available for children aged 5-11 is not likely to have a significant impact in the short term on the current high rate of infection and the number of hospital admissions.

The Committee stresses the importance of providing clear information for parents and children and of avoiding all forms of inducement. The Committee believes that parents' decision whether or not to have their child vaccinated against COVID-19 must not result in the exclusion of children from school or social activities.



The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity.

The reports are available to the public.

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