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Independent report

JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 4 August 2021

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Introduction

The Joint Committee on Vaccination and Immunisation (JCVI) has previously advised COVID-19 vaccination of all adults aged 18 years and over in the UK (https://www.gov.uk/government/publications/covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-jcvi-statement), and vaccination of some specific groups under the age of 18 years (https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020). The COVID-19 immunisation programme has been highly successful, with rapid delivery and high uptake. The programme has already substantially reduced the risk from severe COVID-19 in the UK population and is estimated to have averted approximately 22 million infections and 60,000 deaths to date (https://www.gov.uk/government/publications/covid-19-vaccine-surveillance-report). JCVI developed initial advice on vaccination of children and young people on 2 July 2021. Following consideration by policy makers, that advice was published on 19 July 2021 (https://www.gov.uk/government/publications/covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-jcvi-statement). In view of the progress in offering COVID-19 vaccination to all adults and recent changes to the epidemiology of COVID-19 in the UK, the UK Chief Medical Officers requested JCVI to accelerate its planned review of advice for children and young people.

On 29 July 2021, JCVI deliberated on the potential harms and benefits of vaccinating persons aged 12 to 17- years-old, taking into consideration the latest available data pertaining to children and young people, including:

- the incidence and severity of suspected adverse events following vaccination
- the potential impacts of COVID-19 vaccination on the delivery of other school-based immunisations
- the potential protection provided by vaccination against severe COVID-19 (hospitalisations and deaths), Paediatric Inflammatory Multisystem Syndrome temporally associated with SARS-CoV-2 (PIMS-TS) and post-COVID-19 syndrome
- the mental health and educational impacts of COVID-19
- the seroprevalence of SARS-CoV-2 infection in the UK
- mathematical models of the impact of COVID-19 vaccination on the epidemiology of the pandemic
- the differential impacts of potential harms and benefits on children and young people from more disadvantaged or deprived backgrounds

When formulating advice in relation to childhood immunisations, JCVI has consistently held that the main focus of its decision should be the benefit to children and young people themselves, weighed against any potential harms from vaccination to children and young people. In providing its advice, JCVI also recognises that in relation to childhood immunisation programmes, the UK public places a higher relative value on safety compared to benefits[footnote 1].

Vaccine choice

At this time, the Pfizer-BioNTech BNT162b2 vaccine (https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-of-product-characteristics-for-covid-19-vaccine-pfizerbiontech) is the only vaccine authorised for persons aged 12 to 17 years in the UK. The Conditional Marketing Authorisation for Pfizer-BioNTech BNT162b2 came into effect on 9 July 2021 (https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-of-product-characteristics-for-covid-19-vaccine-pfizerbiontech), with approval previously being provided under Regulation 174

(https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-of-product-characteristics-for-covid-19-vaccine-pfizerbiontech). JCVI advises that only UK authorised COVID-19 vaccines should be offered to those aged less than 18 years.

Vaccine safety

The Pfizer-BioNTech BNT162b2 vaccine is administered via intramuscular injection, usually in the upper arm. The most frequent adverse reactions following vaccination in persons aged 12 to 17 years are injection site pain, fever and headache. These reactions are generally mild, self-limiting and short-lived, typically lasting 1 to 2 days[footnote 2].

In recent weeks, reports have been submitted in the UK and other countries of the extremely rare occurrence of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021), following the use of Pfizer-BioNTech BNT162b2 and Moderna mRNA- 1273 vaccines[footnote 3]. These extremely rare adverse reactions have been more frequent shortly after the second dose, and in younger individuals and males; data from the United States indicate about 60 reported cases per million second doses in younger males, with reporting rates after the first dose being 6 to 7-fold lower (https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm)[footnote 4]. The mechanism of action underlying these rare events is not currently known. Israel and the United States have reported most of the cases and experience from these countries indicate that the reported cases of myocarditis following mRNA vaccination are of a ‘milder phenotype’ (https://www.cdc.gov/vaccines/acip/index.html) with the vast majority of persons recovering swiftly from the acute episode, compared to more typical cases of myocarditis (which are mostly viral or idiopathic in aetiology). Follow up of reported cases in Israel and the United States is on-going. These reports will continue to be closely evaluated by MHRA and JCVI. See MHRA reports on COVID-19 vaccines (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions).

Benefits of vaccination

COVID-19 disease in children is typically mild or asymptomatic. Using serological markers as a measure of prior SARS-CoV2 infection, provisional data from the most recent round of testing in secondary school-aged children in England (early July) indicate the proportion of students testing antibody positive is approximately 40%[footnote 5].

The incidence of severe outcomes from COVID-19 in children and young people is very low. In England, between February 2020 and March 2021 inclusive, fewer than 30 persons aged less than 18 years died because of COVID-19, corresponding to a mortality rate of 2 deaths per million (https://www.medrxiv.org/content/10.1101/2021.07.07.21259779v1). During the second wave of the pandemic in the UK, the hospitalisation rate in children and young people was 100 to 400 per million. Children and young people at higher risk of severe COVID-19 include those with severe neuro-disabilities, Down’s Syndrome, underlying conditions resulting in immunosuppression, profound and multiple learning disabilities (PMLD) (https://www.nhs.uk/conditions/learning-disabilities/), severe learning disabilities or who are on the learning disability register. The data source for this is from OpenSAFELY (https://www.opensafely.org/).

Efficacy of the Pfizer-BNT162b2 vaccine against symptomatic COVID-19 was 100% in the clinical trial involving persons aged 12 to 15 years. The trial was too small to assess the efficacy against severe COVID-19 in 12 to 15 year olds[footnote 2].

Paediatric Inflammatory Multisystem Syndrome Temporally associated with SARS-COV2 infection (PIMS-TS), also called Multisystem Inflammatory Syndrome in Children (MIS-C), is a rare inflammatory disorder occurring after recent SARS-CoV2 infection. In the UK, between March 2020

and July 2020, there were 449 cases of PIMS-TS in persons aged <16 years. Forty-four percent were admitted to paediatric intensive care and the overall case fatality ratio was 1.1%[footnote 6]. Much remains unknown regarding the epidemiology of PIM-TS and its underlying cause. There are no clinical trial data of vaccine efficacy against PIMS-TS, nor any real-world estimates of vaccine effectiveness.

Post-COVID-19 syndrome (often called 'long COVID') (https://www.nice.org.uk/guidance/NG188) has been reported in children and young people. Existing studies suggest that longer term (≥8 weeks) symptoms following SARS-CoV2 infection occur in about <1% to 10% of persons after COVID-19, with controlled studies generally reporting rates at the lower end of this range (https://doi.org/10.1101/2021.05.05.21256649)[footnote 7]. As vaccination protects against COVID-19, it is expected that vaccination will also provide some protection against the development of post-COVID-19 syndrome, although estimates of vaccine effectiveness are not available.

Mental health and educational impacts of COVID-19 on children and young people are widely recognised. Some school-based isolation measures have had a disproportionate impact on education, and may also affect mental health. National advice regarding school-based isolation measures is currently under review although JCVI recognises that there will be heterogeneity in the individual responses of children, parents, head teachers and schools to any advice. The extent to which vaccination may mitigate the mental health and educational impacts of COVID-19 on children and young people is difficult to quantify.

Modelling from the University of Warwick[footnote 8] and from Public Health England[footnote 9] indicate that vaccinating children and young people could have some impact on hospitalisations and deaths in older adults. The extent of such benefits is highly uncertain. By autumn 2021, all eligible adults should have been offered 2 doses of COVID-19 vaccine. A successful adult COVID-19 immunisation programme would mean that education staff and adult household members of pupils and students should have been vaccinated, reducing the risk of onward transmission from children to adults in school or at home, respectively.

Wider health implications and operational considerations

Following disruptions in routine immunisation programmes because of the pandemic, there is an urgent need to catch-up on non-COVID-19 school immunisations such as human papillomavirus (HPV) and meningitis (MenACWY) vaccinations, and there may be a need to offer other routine vaccines (such as mumps, measles and rubella (MMR)) in the school setting as part of overall recovery. In addition, for 2021 to 2022, the childhood influenza programme has been extended (https://acmedsci.ac.uk/policy/policy-projects/covid-19-looking-ahead-to-winter-2021-22-and-beyond) in the expectation that influenza activity may be earlier and more pronounced this year. The health benefits from these various non-COVID-19 school-based immunisation programmes are well established, and some may provide the last effective opportunity to complete an individual's immunisation course and provide timely and/or lifelong protection. Further deferral of the delivery of these immunisation programmes may be associated with permanent decreases in uptake of these vaccines in affected school age cohorts.

Delivery of a COVID-19 vaccine programme for children and young people is likely to be disruptive to education in the short-term, particularly if school premises are used for vaccination. Adverse reactions to vaccination (such as fevers) may also lead to time away from education for some individuals.

Considerable additional resource will be required to minimise the operational impacts of a COVID-19 vaccine programme on the wider health of children and young people.

Current advice

For adults aged 18 years and over, JCVI considers that the potential benefits of vaccination with Pfizer-BNT162b2 continue to outweigh potential harms.

For persons aged <18 years old who do not have underlying health conditions that put them at higher risk of severe COVID-19, there is more uncertainty in the precision of the harm-benefit balance when considering the impacts on children and young people themselves. As with adults, age has a strong influence. In general, older children are more likely to benefit from vaccination compared to younger children.

At this time, JCVI advises that all 16 to 17-year-olds should be offered a first dose of Pfizer-BNT162b2 vaccine. This is in addition to the existing offer of 2 doses of vaccine to 16 to 17-year-olds who are in 'at-risk' groups (https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a). Pending further evidence on effectiveness and safety in this age group, a second vaccine dose is anticipated to be offered later to increase the level of protection and contribute towards longer term protection (https://doi.org/10.1101/2021.07.26.21261140). Further data and the potential availability of alternative vaccine options will inform exact details which will be provided in a subsequent update of this advice before second doses are due at approximately 12 weeks after the first dose.

As previously advised by JCVI, persons aged 12 to 15 years with specific underlying health conditions that put them at risk of severe COVID-19, should be offered 2 doses of Pfizer-BNT162b2 vaccine with an interval of 8 weeks between doses. This currently includes children with severe neuro-disabilities, Down's Syndrome, underlying conditions resulting in immunosuppression, profound and multiple learning disabilities (PMLD) (https://www.gov.uk/government/publications/covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-jcvi-statement), severe learning disabilities or who are on the learning disability register. Details regarding additional person-groups with underlying health conditions to be offered vaccination will be provided as updates in the Green Book (https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a).

Children and young people aged 12 years and over who are household contacts of persons (adults or children) who are immunosuppressed should be offered 2 doses of Pfizer-BNT162b2 vaccine on the understanding that the main benefits from vaccination are related to the potential for indirect protection of their household contact who is immunosuppressed. The offer of vaccination may help to alleviate stress and anxiety experienced by the children and young people living in these difficult circumstances. This advice is provided recognising that persons who are immunosuppressed are at higher risk of serious disease from COVID-19 and may not generate a full immune response to vaccination themselves[footnote 10].

Further data and experience relevant to the vaccination of otherwise healthy persons aged 12 to 15 years are accumulating. The current epidemiology of COVID-19 in the UK is also changing rapidly. JCVI considers these factors important in determining the overall harm-benefit balance related to the vaccination of healthy 12 to 15 year olds. JCVI will continue to review emerging data and provide further advice in a timely manner.

In all instances, the offer of vaccination to children and young people must be accompanied by appropriate information to enable children and young people, and those with parental responsibility, to be adequately appraised of the potential harms and benefits of vaccination as part of informed consent prior to vaccination.

Future advice

Clinical trials are underway in pre-school and primary-school aged students. Vaccines are only likely to be approved for use in these age groups after summer 2021. JCVI will continue to update its advice as new data emerge.

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