Department of Health & Social Care

Independent report

Joint Committee on Vaccination and Immunisation (JCVI) advice on COVID-19 vaccination in people aged 16 to 17 years: 15 November 2021

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Introduction

The Joint Committee on Vaccination and Immunisation (JCVI) has previously advised:

- 2 doses of the Pfizer-BioNTech COVID-19 vaccine in children and young people aged 16 to 17 years with an underlying health condition that places them at higher risk from serious COVID-19 (‘at-risk group’)
- a first dose of Pfizer-BioNTech COVID-19 vaccine for those not in an at-risk group

On 19 October 2021 JCVI considered options for offering a second dose to persons aged 16 to 17 years who are not in an at-risk group.

Advice

JCVI advises that young people aged 16 to 17 years who are not in an at-risk group should be offered a second dose of Pfizer-BioNTech (Comirnaty) COVID-19 vaccine.

The second vaccine dose should be given 12 weeks or more following the first vaccine dose.

For persons who have had proven SARS-CoV-2 infection and a first dose of vaccine, the second vaccine dose should be given 12 weeks or more following the first vaccine dose, or 12 weeks following SARS-CoV-2 infection, whichever is later.

Communications

Individuals should receive information on the potential risks and benefits of vaccination to allow them to make a cognisant decision about whether and when to accept the second dose based their own personal circumstances.

Considerations

The evidence considered by JCVI in relation to the vaccination of persons aged 16 to 17 years who are not in an at-risk group included data on:

- the risk of symptomatic disease, hospitalisation, Paediatric Intensive Care Unit (PICU) admission, mortality and paediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-2 (PIMS-TS) following SARS-CoV-2 infection
- the effectiveness of COVID-19 vaccination in preventing infection, symptomatic disease, hospitalisation, intensive care admission and mortality, and the prevention of PIMS-TS and 'long COVID'[footnote 1] through protection against infection and disease
- the incidence and severity of suspected adverse events following vaccination in children, young people and young adults, including data on the risk of myocarditis following vaccination from the UK, Europe, Israel, the USA and Canada
- the seroprevalence of SARS-CoV-2 infection in children and young people in the UK
- a risk-benefit analysis undertaken by the UK Health Security Agency (UKHSA)

When formulating advice in relation to childhood immunisations, JCVI has consistently held that the main focus of its considerations should be the benefit to children and young people themselves, balanced against any potential harms from vaccination to children and young people; the population level impact of

vaccinating this age group has not been considered in the development of this advice.

Young people aged 16 and 17 years are moving towards adulthood, higher education and/or the workplace and are currently at a pivotal point in their education. Their social behaviour and social mixing patterns are different compared to younger children. Persons aged 16 to 17 years can usually provide informed consent for their own vaccination.

In providing its advice, JCVI recognises that the public typically place a higher relative value on vaccine safety compared to vaccine benefits (Luytens and others). In the situation of a pandemic, additional factors such as the impact of vaccination on travel, access to social events and activities, and attendance in education during key milestones in further education, may also be important to some individuals. There are strong feelings both for and against vaccination of children and young people. Many young people will want to protect themselves fully against COVID-19, and may also want to protect vulnerable close contacts, such as older relatives. JCVI considers that individual value judgements around vaccination are important, and this is upheld through the system of informed consent within the UK national immunisation programme.

The impact of the COVID-19 pandemic on the lives of children, young people and adults means that the public is deeply invested in decisions around the COVID-19 vaccination programme. For older adults, there is a large evidence base supporting the benefits of vaccination over potential harms. The benefits and risks from COVID-19 vaccination in children and young people are much more finely balanced largely because the risks associated with the infection are so much lower. There has been particular interest regarding the extremely rare occurrence of myocarditis (inflammation of the heart muscle) following vaccination reported in younger adults.

Background

Benefits of vaccination

A single dose of COVID-19 vaccine offers good short-term protection against infection and symptomatic disease from SARS-CoV-2 and very good protection against severe disease and death (Andrews N and others, September, 2021) There is some data to indicate that the duration of protection from the first vaccine dose in otherwise healthy younger adults extends through 16 weeks (Carazo, Sara, Clinical Infectious Diseases, August 2021). Children and young people generally mount more robust immune responses to vaccination than adults. Hence, although data on waning after a single vaccine dose in children and young people specifically is limited, the expert view of JCVI is that protection from a

single dose of vaccine can be expected to endure for at least as long as for young adults. A second vaccine dose increases the level of protection and is important for extending the duration of protection (Table 1).

Key benefits of a second dose of vaccine, compared to a single dose, include:

- more durable protection against COVID-19
- a further reduction in the risk of serious COVID-19, including, hospitalisation and intensive care unit admission
- a further reduction in the risk of infection and symptomatic disease, which may also reduce the risk of PIMS-TS, 'long COVID' and onwards transmission to vulnerable close contacts

Table 1: benefits of COVID-19 vaccination in children and young people not in an at-risk group; based on 30% infection rate in those not previously infected and 9% in those previously infected (overall ~ 20% rate), taking into account protection from prior infection (19 October 2021) – based on UK data

Prevented per million first vaccine doses:

Age (years)	PICU admission	Hospital admission	PIMS-TS
12-15	3.6	131	23
16-17	1.2	115	17

Prevented per million second vaccine doses:

Age (years)	PICU admission	Hospital admission	PIMS-TS
12-15	0.2	9	19
16-17	0.1	8	14

Prevented per course:

Age (years)	PICU admission	Hospital admission	PIMS-TS
12-15	3.8	139	42
16-17	1.3	123	31

Risks of vaccination

There have been suspected adverse reaction reports submitted via the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card scheme in the UK and equivalent reporting systems in other countries of the extremely rare occurrence of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart), and the reporting rates for these are higher following the use of COVID-19 mRNA vaccines: Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax) vaccines.

Reporting rates from individual countries have varied widely, likely reflecting differences in health systems, vaccine safety surveillance systems, case ascertainment, vaccination programme and other factors. Consistent features include a higher reporting rate in adults aged less than 40 years compared to older adults, and a higher rate in males compared to females. Reports from the USA and Israel indicate a higher reporting rate with the second vaccine dose compared to the first vaccine dose; in these countries the second vaccine dose is typically given 3 to 4 weeks following the first dose (Table 2). There is some data to suggest that a longer interval (more than 8 weeks) between first and second doses, as used in the UK, is associated with a lower myocarditis reporting rate following the second vaccine dose (Table 3).

Table 2: myocarditis reporting rate following vaccination, per million vaccinations administered – reporting rate ranges based on data from different countries (until 19 October 21)

Age (years)	Dose 1	Dose 2
12-15	2.6 to 17.7	20.9 to 42.2
16-19	2.5 to 9.4	12.0 to 81.4

Table 3: reporting rate of suspected myocarditis and pericarditis per million doses of Pfizer-BioNTech vaccine in the UK (data from MHRA up to 27 October 2021)

Age (years)	Dose 1/unknown dose	Dose 2
18-29	21	20

Notes on Table 3:

1. Up to and including the 27 October 2021, the reporting rate for suspected myocarditis and pericarditis occurring after either dose of Pfizer-BioNTech (Comirnaty) vaccine in those under 18 years is 9 suspected adverse reactions per million doses. There is currently insufficient data to calculate a precise estimate of the reporting rate post-dose 2 in under 18 year olds in the UK due to, as yet, relatively limited exposure of dose 2 in these individuals. Available data indicates the reporting rate in under 18 year olds is not higher than that in the 18 to 29 year age group.
2. This data refers to suspected adverse reaction reports. Most reports in both the adult and under 18 years age group describe mild symptoms and individuals have recovered with standard treatment.

The available data indicates that the clinical manifestations of myocarditis following vaccination are typically self-limiting and resolve within a short time. It is not known if there are any long-term sequelae (months to years) from myocarditis. The current overall reporting rate of myocarditis and pericarditis in those under 18 years (9 suspected adverse reactions per million doses of Pfizer-BioNTech vaccine) is lower than that in the 18 to 29 year age group.

There is evidence that SARS-CoV2 infection is also associated with the occurrence of myocarditis. The mechanisms underlying myocarditis following SARS-CoV2 infection versus COVID-19 vaccination are not understood at present; these mechanisms and their consequences may be different, and therefore direct comparisons between these 2 forms of myocarditis cannot be assumed.

Key risks from a second dose of COVID-19 vaccine include:

- post-vaccination reactogenicity, such as short-lived pain at the injection site, headache and fever – these are typically mild and resolve in a few days
- post-vaccination myocarditis (extremely rare)

Vaccine choice

In the UK, first vaccine doses for persons aged 16 to 17 years old have been with the Pfizer-BioNTech (Comirnaty) vaccine. Some data from Europe, Canada and the USA suggests that reporting rates of post-vaccination myocarditis are higher following receipt of the Moderna (Spikevax) vaccine, compared with the Pfizer-BioNTech (Comirnaty) vaccine. These findings pertain to both homologous (that is, use of the same vaccine for first and second dose) use of Moderna (Spikevax) vaccine in the primary 2-dose schedule and heterologous use (use of different vaccines for the first and second dose, Comirnaty followed by Spikevax)

compared to homologous Pfizer-BioNTech (Comirnaty) vaccination.

Interval between doses

Evidence from Pfizer-BioNTech (Comirnaty) vaccination in adults indicates that an extended interval (8 to 12 weeks as compared to 3 to 4 weeks) between first and second doses is associated with higher vaccine-induced immune responses and higher levels of vaccine effectiveness in the short term (Skowronski DM and others, October 2021; Amirthanilgam G and others, July 2021). Higher peak levels of protection may also influence the duration of protection. Similar effects can be expected in persons aged 16 to 17 years.

Data from Canada, Europe and the UK further suggests that an extended dose interval may reduce the risk of myocarditis from the second vaccine dose, although a causal association between dose interval and risk from myocarditis following vaccination has not yet been established.

Prior SARS-CoV2 infection

In persons who have had prior SARS-CoV2 infection, the first dose of vaccine stimulates a higher level of immune responses often comparable to, or greater than, 2 doses of vaccine. (Appleman B and others, September, 2021; Krammer F and others, March 2021). The resulting protection against serious COVID-19 might therefore be expected to be as good as 2 doses of vaccine. However, there are as yet no clinical studies to confirm this and there is also limited data on the duration of protection that ensues. The nature of immune responses in persons who have had a single dose of vaccine and subsequently develop SARS-CoV2 infection is still under investigation.

Available data does not indicate an elevated risk of myocarditis following vaccination in persons with prior SARS-CoV2 infection. Nonetheless, taking a precautionary stance, JCVI is of the view that allowing a longer interval (12 weeks) between any recent SARS-CoV2 infection and a second vaccine dose is a reasonable measure to optimise safety without particular loss in benefit in this age group.

Comparing the risks and benefits

Overall, the view of JCVI is that there is more certainty in the data regarding the benefits from vaccination compared to the data regarding the risks. In particular, information regarding any longer-term (months to years) consequences of post-vaccination myocarditis remains unclear and such information will only become available with the passage of time.

When considering these risks and benefits, the very small numbers of people with

serious outcomes following infection or following vaccination means there is a high level of imprecision in the estimates. The speed and level of waning of protection following a single dose of vaccine is an additional important factor for which data, especially beyond 16 weeks, is limited. The greater the level of waning of first-dose protection, the greater the benefits from the second vaccine dose.

In the coming months, further data is expected in relation to the benefits from first and second vaccine doses and myocarditis reporting rates following vaccination. In addition, other options for second dose vaccination may become available, such as the use of lower doses of vaccine which may be associated with fewer vaccine-related reactions. The effect of prior SARS-CoV2 infection in association with a single dose of COVID-19 vaccination, and whether the level of protection this provides is comparable to 2 doses of vaccine, may also become clearer. This new data will inform further advice from JCVI. Individuals who wish to consider deferring their second vaccine dose until more data becomes available, or further advice is developed, should also take into account the likelihood of continuing uncertainties in future data and the course of the pandemic.

More details on the risks and benefits of vaccination are summarised in previous advice from JCVI (August 2021).

Informed consent

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 apprised of the potential harms and benefits of vaccination as part of informed consent prior to vaccination. UKHSA produces leaflets for children and parents on COVID-19 vaccines, including information on the risk of myocarditis.

Teams responsible for the implementation and deployment of COVID-19 vaccination for persons aged 16 to 17 years should be appropriately trained and confident regarding the information relevant to the vaccination of these persons.

Future advice

First doses of COVID-19 vaccine are currently being offered to children and young people aged 12 to 15 years. JCVI aims to provide advice on second doses of vaccine in those aged 12 to 15 years, when additional data on the risks and benefits of vaccination may be available.

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 in the UK in

late 2021 or early 2022. JCVI will provide advice on vaccination of younger children in a timely way, relative to any UK authorisation in younger children.

Key evidence considered

Risk of myocarditis following vaccination:

- MHRA reports of suspected myocarditis following vaccination (and unpublished data)
- CDC reports of myocarditis following vaccination (and unpublished data)
- Reported side effects following COVID-19 vaccination in Canada
- Public Health Ontario data on myocarditis following vaccination (and unpublished data)

NORDIC data on myocarditis following COVID-19 vaccination (unpublished):

- Mevorach and others. Myocarditis after BNT162b2 mRNA vaccine against COVID-19 in Israel
- Witberg and others. Myocarditis after COVID-19 vaccination in a large health care organization
- Barda and others. Safety of the BNT162b2 mRNA COVID-19 vaccine in a nationwide setting
- Jain and others. COVID-19 vaccination-associated myocarditis in adolescents
- Hoeg and others. SARS-CoV-2 mRNA vaccination-associated myocarditis in children ages 12-17: a stratified national database analysis
- Mouch and others. Myocarditis following COVID-19 mRNA vaccination

Risk of myocarditis following infection:

- Patone and others. Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection (unpublished)
- Singer and others. Risk of myocarditis from COVID-19 infection in people under age 20: a population-based analysis
- Patel T and others. Comparison of MIS-C related myocarditis, classic viral myocarditis, and COVID-19 vaccine related myocarditis in children.

Vaccine efficacy and effectiveness against infection, symptomatic disease, hospitalisation and mortality:

- UKHSA COVID-19 weekly vaccine surveillance reports
- Frenck and others. Safety, immunogenicity, and efficacy of the BNT162b2 COVID-19 vaccine in adolescents.
- Miron O and others. Effectiveness of COVID-19 vaccine BNT162b2 at age 12-15 years with one dose (Israel)

- Andrews N and others. Vaccine effectiveness and duration of protection of Coirnaty, Vaxzevria and Spikevax against mild and severe COVID-19 in the UK

Risk of symptomatic disease, hospital admission, PICU admission, and mortality:

- Ward and others. Risk factors for intensive care admission and death amongst children and young people admitted to hospital with COVID-19 and PIMS-TS in England during the first pandemic year
- Smith and others. Deaths in children and young people in England following SARS-CoV-2 infection during the first pandemic year: a national study using linked mandatory child death reporting data
- Harwood and others. Which children and young people are at higher risk of severe disease and death after SARS-CoV-2 infection: a systematic review and individual patient meta-analysis

Single dose in those with prior infection and protection following infection:

- Amirthalingam and others. Higher serological responses and increased vaccine effectiveness demonstrate the value of extended vaccine schedules in combatting COVID-19 in England
- Sokal and others. Maturation and persistence of the anti-SARS-CoV-2 memory B cell response
- Dan and others. Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. Science
- Gallais and others. Anti-SARS-CoV-2 antibodies persist for up to 13 months and reduce risk of reinfection
- Appelman and others. Time since SARS-CoV-2 infection and humoral immune response following BNT162b2 mRNA vaccination

Long COVID:

- Radtke and others. Long-term symptoms after SARS-CoV-2 infection in children and adolescents
- Stephenson and others. Long COVID – the physical and mental health of children and non-hospitalised young people 3 months after SARS-CoV-2 infection; a national matched cohort study (The CLoCk) Study
- Molteni E, and others. Illness duration and symptom profile in symptomatic UK school-aged children tested for SARS-CoV-2.

PIMS-TS:

- Flood and others. Paediatric multisystem inflammatory syndrome temporally associated with SARS-CoV-2 (PIMS-TS): Prospective, national surveillance, United Kingdom and Ireland

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1. ‘Long COVID’ includes post-COVID-19 syndrome and Long COVID (National Institute for Health and Care Excellence guideline). ↩

Coronavirus (COVID-19)

Coronavirus (COVID-19): guidance and support

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