14 September 2021

Llywodraeth Cymru
Welsh Government

# 12-15 years old vaccination Q&A Version

**1. What advice did the Minister consider in making the decision to offer a vaccination to 12-15 yr olds?**

- The JCVI provided advice to the Minister on 3rd September stating that the health benefits of vaccinating healthy 12-15 year olds slightly outweighed the risks however the margin was too small to recommend vaccination on health grounds alone.

- The margin of benefit, based primarily on a health perspective, is considered too small to support advice on a universal programme of vaccination of otherwise healthy 12 to 15-year-old children at this time. The JCVI therefore suggested that the Government may wish to seek further views on the wider societal and educational impacts from the Chief Medical Officers (CMOs) of the four nations, with representation from JCVI in these subsequent discussions.

- As suggested by the JCVI the UK CMOs then looked at these wider public health benefits and risks of universal vaccination in this age group.

- Of these, the most important was impact on education. UK CMOs also considered impact on mental health and operational issues such as any possible negative impact on other vaccine programmes, noting the importance of other routine immunisations of children and young people, and that the annual flu vaccine deployment programme commences imminently

- The UK CMOs consider education one of the most important drivers of improved public health and mental health. Evidence from clinical public health colleagues consistently makes clear the massive impact that absent or disrupted face-to-face education has had on the welfare and mental health of many children and young people.

- Overall, the view of the UK CMOs was that the additional likely benefits of reducing educational disruption, and the consequent reduction in public health harm from educational disruption, on balance provided sufficient extra advantage in addition to the marginal advantage at an individual level identified by the JCVI to recommend in favour of vaccinating this group. **They therefore recommend on public health grounds that Ministers extend the offer of universal vaccination with a first dose of Pfizer-BioNTech COVID-19 vaccine to all children and young people aged 12-15 not already covered by existing JCVI advice.**

- Published advice here: https://www.gov.uk/government/publications/universal-vaccination-of-children-and-young-people-aged-12-to-15-years-against-covid-19

- The Minister for Health and Social Services considered both pieces of advice and with the JCVI and CMO both saying there was a benefit to this age range, agreed to offer the vaccine from the end of September.

**Why not recommend two doses as with at risk groups?**

- In line with the approach taken for healthy 16-17 year olds UK CMOs would want the JCVI to give a view on whether, and what, second doses to give to children and young people aged 12-15 once more data on second doses in this age group have accrued internationally. This will not be before the Spring Term.

## JCVI advice of 3 September

**2. Did JCVI advise against the universal vaccination of children aged 12-15?**

- The JCVI has advised that the health benefits of vaccinating people in this age group outweigh the risks, but not sufficiently enough to recommend a universal programme on health grounds. It has advised the government may wish to seek further views on the wider societal and educational impacts from the Chief Medical Officers of the four nations, with representation from JCVI in these subsequent discussions.

**3. Why did the JCVI decide the benefits of vaccination outweighed the harms and recommend an initial vaccine dose for those aged 16-17 but while agreeing the benefits also outweighed the harms for 12-15 year olds conclude the health benefit for this age group was too marginal to recommend vaccination. What's the difference?**

- 16 and 17 year olds are moving towards adulthood, higher education and/or the workplace. Their social behaviour and social mixing patterns are different compared to children aged 12 to 15 years, and throughout the pandemic rates of infection have been consistently higher in 16 to 17-year olds compared to younger children. Those aged 16-17 years can also provide informed consent for their own vaccination.

**4. If there are not clear health benefits, why did the committee refer to the UK CMOs to provide further advice?**

- The JCVI is constituted with expertise to allow consideration of the direct health benefits and risks of vaccination, and it is not within its remit to incorporate in-depth considerations on wider societal impacts, including educational benefits.

- JCVI has therefore advised that the Government take further advice from the CMOs of the UK's four nations, with representation from JCVI in these subsequent discussions, to enable a fuller consideration of potential additional benefits of vaccination in children and young people such as wider public health or societal benefits, including educational impacts.

- Accepting the advice of the JCVI, the four health Ministers requested that the UK CMOs take forward work to consider the matter from a broader perspective, as recommended by the JCVI. Accordingly, the UK CMOs looked at wider public health benefits and risks to determine if this shifts the risk-benefit balance either way. Of these, the most important in this age group was impact on education.

**5. Does the Government have to follow JCVI advice?**

- The JCVI is an independent advisory committee with functions in both England and Wales. The role of an advisory committee under section 189 of the 2006 Act is to advise the Welsh Ministers on such services provided under the 2006 Act, while they are not bound to follow that advice there would be need to be a clear and reasoned rationale for not doing so in order to mitigate the risk of any challenge on public law grounds.

- JCVI recommendations relating to the COVID-19 vaccines are not binding under the Health Protection (Vaccine) Regulations 2009, as the JCVI has not undertaken a cost-effectiveness analysis. However, the JCVI are an expert body who have given scrutiny of the relevant evidence. Following the JCVI recommended approach is objectively rational.

**6. Why would the CMOs recommend offering universal vaccination to children aged 12-15 even though the JCVI think there is no clear overall benefit from a medical or clinical perspective?**

- JCVI's recommendation is based primarily on a health perspective. The CMOs of the four nations, with representation from JCVI in these subsequent discussions, looked at wider health benefits and risks of universal vaccination in this age group to determine if this shifts the risk-benefit balance either way.

- Of these, the most important in this age group was education. The effects of disrupted education, or uncertainty, on mental health are well recognised. There can be lifelong effects on health if extended disruption to education leads to reduced life chances.

**7. When will all offers be made and what does an 'offer' actually mean?**

- The intention is to offer all 12-15 yr olds an appointment and to vaccinate all who choose to come forward **by October half term**.

- Vaccinations will take place predominantly in vaccinations centres on evenings and weekends, and in some schools. The intention is to cause the least disruption possible to the young people's education, as is the intention of offering the vaccination. Through this blended model, **we will be able to begin to offer the vaccination as quickly as the 27 Sept**.

**8. Will children be vaccinated to protect adults?**

- No. Vaccination decisions for children are made on the basis of the risk and benefits to this age group only – both JCVI and CMOs have been very clear on this.

- When considering the evidence for this advice, UK CMOs looked at wider public health benefits and risks in this age group. Of these, the most important for this age group was impact on education. Evidence from clinical and public health colleagues, general practice, child health and mental health consistently makes clear the massive impact that absent or disrupted face-to-face education has on the welfare and mental health of many children and young people.

- On balance, UK CMOs consider that it is likely that vaccination will help reduce transmission of COVID-19 in schools. Having a significant proportion of pupils vaccinated will help reduce outbreaks in or associated with schools. This will also reduce the risk of an individual child contracting COVID-19. This means vaccination is likely to reduce education disruption, which will directly improve the mental health and life chances of young people.

**9. Which 12-15 year olds are currently eligible for vaccination?**

- On 19 July, JCVI advised that children aged 12 and over with severe neuro-disabilities, Down's Syndrome, underlying conditions resulting in immunosuppression, profound and multiple learning disabilities (PMLD), severe learning disabilities or who are on the learning disability register, should be offered COVID-19 vaccination. On 3 September, further eligible conditions were added to the Public Health England Green Book, including haematological malignancy, sickle cell disease, type 1 diabetes, and congenital heart disease. The full list of health conditions can be found here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1015203/Greenbook_chapter_14a_3Sept21.pdf

- The JCVI also advised in its advice of 19th July that healthy 12-15-year olds who are household contacts of immunosuppressed individuals of any age should be offered vaccination. The primary aim of this is to protect the immunosuppressed individual.

- The JCVI has advised that the health benefits of vaccinating people in this age group outweigh the risks, but not sufficiently enough to recommend a universal programme on health grounds. It has advised the government may wish to seek further views on the wider societal and educational impacts from the Chief Medical Officers of the four nations, with representation from JCVI in these subsequent discussions.

**10. Why have further 'at risk' groups been added for the 12-15 age group?**

- Throughout the pandemic, the JCVI has kept its advice on COVID-19 vaccines under review. This includes its position on vaccinating 'at-risk' groups aged 12-15.

**11. Are children aged 12-15 with asthma included in the 'at risk' groups?**

- The JCVI advises that persons with poorly controlled asthma should be offered a course of COVID-19 vaccination.

**12. Will those in 'at risk' groups receive two or three doses?**

- Those aged 12 and above who are in an 'at risk' group will be offered a two-dose primary schedule unless the individual is severely immunosuppressed, in which case a three-dose primary schedule is advised in accordance with the latest JCVI advice on third primary vaccine doses contained in the Public Health England Green Book, Chapter 14a: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1015203/Greenbook_chapter_14a_3Sept21.pdf

**Operational Delivery**

**13. Where and when will healthy 12-15 year olds receive the vaccine?**

- Health Boards in Wales have been planning for the vaccination of this age group since May, to be prepared if this decision was ever taken. Therefore, preparations for the vaccination of this group are well underway.

- Healthy school-aged children 12-15 will primarily receive their COVID-19 vaccination in vaccination centres with some health boards offering through schools.

**14. Who will vaccinate the child?**

- The Oversight will be by experienced child vaccinators with registrants vaccinating - As per current vaccination of children procedures.

- There will also be staff with experience of vaccinating children and young people rostered in the Vaccination Centres.

## Safety considerations

**15. Which vaccines will be offered to 12-15 year olds?**

- The Pfizer BioNTech vaccine has approval for use from 12 years old and currently has the most extensive safety data in those aged 12-15 years. This vaccine is therefore the preferred vaccine in this age group.

**16. Why did the UK CMOs only recommend vaccinating with Pfizer, when the MHRA have approved Pfizer and Moderna for those aged over 12?**

- This advice followed the current advice from JCVI that Pfizer BioNTech is the preferred vaccine for those aged under 18. The JCVI has seen fuller safety data for Pfizer for this age group and at this point in time Pfizer therefore remains the preferred vaccine. The CMOs were asked to look at whether healthy 12-15 year olds should be offered vaccination. Their remit did not include recommending changes to the existing JCVI advice on choice of vaccine for the under 18s.

**17. Will teachers be offered boosters at the same time as children and young people?**

- No.

- The Government has welcomed interim advice from the JCVI on a potential COVID-19 booster vaccination programme which was published on 30 June 2021. The JCVI's interim advice is that COVID-19 boosters are first offered to the most vulnerable. Teachers will only be offered boosters if there is a decision to launch a booster programme and the individual teacher meets the criteria for a booster. The adult programme, including boosters is separate from this new initiative to offer primary vaccination to children and young people.

- Final decisions on the timing and scope of the COVID-19 vaccine booster programme will be made shortly informed by further independent advice from the JCVI.

**18. Will teachers who have not yet taken up their offer for vaccination (first or second dose) be able to get vaccinated in schools?**

- No, 93% of all school staff are already double vaccinated. There are walk in centres across Wales where no appointment is needed for anybody who hasn't yet had their first or second vaccine (as long as there is an 8 week interval).

**19. Will seasonal flu and COVID-19 vaccines be co-administered by School-Age Immunisation Services (SAIS) teams in schools?**

- No, the primary model of delivery in Wales is through vaccination centres. There are some schools involved where it might be possible. The JCVI has confirmed that the co-administration of COVID-19 and seasonal flu vaccines is possible, however, the timing may not allow for this.

## Consent

### 20. Can children aged 12-15 provide consent for themselves?

- Under 16s are not automatically presumed to be legally competent to make decisions about their healthcare and, therefore, whether they should be given the COVID-19 vaccine. However, the courts have stated that under 16s will be competent to give valid consent to a particular intervention if they have "sufficient understanding and intelligence to understand fully what is proposed" (i.e. Gillick competence).

- If a child is not competent to give consent for themselves, consent should be sought from a person with parental responsibility.

### 21. What is the Gillick competence, and how long has it been used for?

- The Gillick test, (as set out in the case of Gillick v West Norfolk and Wisbech Area Health Authority [1986] AC 112), provides that if a child under the age of 16 has sufficient understanding and intelligence to understand what is being proposed, care and treatment can be provided without parental consent.

- Gillick competence reflects a child's increasing development to maturity.

- Whether or not a child is Gillick competent will depend on whether the child is able to understand the nature and implications of the particular treatment for which consent is sought.

### 22. How is consent for childhood vaccination usually gained?

- For those under 16 years of age, consent to vaccination is sought from a person with parental responsibility. Consent is only needed from one person with parental responsibility as long as there is no dispute about vaccination with any other parent responsible for that child or another person "in loco parentis" where a decision by the courts may be needed.

- Those giving consent on behalf of children must have the capacity to consent to the vaccine, be acting voluntarily and be appropriately informed. Parents should exercise the power to consent in the child's best interests. Even where a child lacks capacity to consent on their own behalf, it is good practice to involve the child as much as possible in the decision-making process.

- It is possible for a parent to give consent on behalf of a Gillick competent child, provided the child does not refuse their consent (in other words, parental consent cannot override a Gillick competent child's objection).

- For vaccination centres, the parent or carer will provide consent when they arrive with the child/young person. They will receive information as part of their invitation letter.

**23. How are children immunised in schools? Is written consent needed?**

- In a secondary school setting, it is common practice for consent forms and information (or links to information), to be sent to the child's parents in advance of the immunisation session. The consent forms may be paper or electronic systems where the parents are emailed to seek consent.

- Whilst consent to vaccination does not need to be in writing, written parental consent is sought in advance as the parents are not usually present at the time of vaccination.

**24. Can schools help secure parental or child consent?**

- Whilst schools may host immunisation services and share factual information (provided by health services), **they are not responsible** for securing parental or child consent, assessing Gillick competence or mediating between parents and children who may disagree about whether or not to consent. This is the role of the School nurses, who have the expertise and experience to handle these issues and whose registered nurses are professionally accountable.

**25. Will govt be consulting with the Royal Colleges on how best to present the risk-benefits of vaccination to children and young people? (As per paragraph 25 of the UK CMOs' advice).**

- The CMOs recommended that the Royal Colleges and other professional groups are consulted in how best to present the risk-benefit decisions about vaccination in a way that is accessible to children and young people as well as their parents. They note that a child centred approach to communication and deployment of the vaccine should be the primary objective. The Covid Vaccines programme is taking this forward – sharing communications for parents and children and young people - before the implementation of the advice.