



Llywodraeth Cymru
Welsh Government

From:

Elin Gwynedd
COVID-19 Vaccination
Programme

Tel Irrelevant & Sensitive

Cleared by:

Elin Gwynedd

Date:

13 September 2021

MINISTERIAL ADVICE

For decision by: Minister for Health and Social Services

Copied to: First Minister, Education Minister and Deputy Minister for Health and Social Services.

Subject	COVID-19 vaccinations for 'healthy' 12-15 year olds.
100 word summary	You are asked to consider the advice from the 4 UK CMOs, alongside the JCVI advice, and make a decision on whether to vaccinate 12-15yr olds who do not have any underlying health conditions and are not identified as 'at risk if they were to contract COVID-19'.
Timing	Very Urgent. A decision is needed as soon as possible to align with the other UK nations and to operationalise and communicate, depending on your decision.
Recommendation	The Minister is asked to <ul style="list-style-type: none"> • consider the advice; • note the options open to you and indicate your preference.
Decision report	This decision does not require a Decision Report as a written statement will be issued.

Background

1. The Joint Committee on Vaccination and Immunisation (JCVI) is an independent expert advisory committee that advises United Kingdom health departments on immunisation, making recommendations concerning vaccination schedules and vaccine safety. It has a statutory role in England and Wales, and health departments in Scotland and Northern Ireland may choose to accept its advice.
2. To date, the JCVI has only recommended that children 12-15 year olds who are at increased risk, severely immunocompromised or in the household of severely immunocompromised individuals should be offered the COVID-19 vaccination, and they should be offered a two dose schedule. You have accepted their advice and these groups have already started to be invited for their first dose.

JCVI's advice on vaccinating healthy children 12-15 yrs

3. The JCVI has discussed at length if children who do not have underlying health conditions (or 'healthy' children), should be offered the vaccine. From the evidence and data they considered, they found that there is a marginal benefit to the child which is greater than the potential known harms, however, there is considerable uncertainty regarding the magnitude of the potential harms. 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. There is some uncertainty about the risks and long term consequences for a very small number of children who may react badly (scarring of the heart). The US, Israel and Canada have all presented and given evidence to the JCVI on their safety signals for this age range and this has been taken into account in the JCVI's final decision. Based on the individual health benefit to the child, the JCVI **did not advise that all healthy 12-15yr olds be vaccinated.**
4. The JCVI were careful in their advice to state that their remit is only to look at the individual health benefit and they realise that there are wider population/societal benefit where the CMO is better placed to advise Ministers i.e. health inequalities, post-covid syndrome, mental health, education, ethics, which are for others to consider.
5. As suggested by the JCVI, you agreed with the other UK Health Ministers to collectively write to ask the 4 UK CMOs to take forward work as soon as possible, drawing on experts as they see fit (including the chair of the JCVI), to consider the matter from a broader perspective.

CMO's Advice on vaccinating healthy children 12-15 yrs

6. The CMO considered what is the fundamental purpose of offering vaccination to all 12-15 year olds?
 - Is it to prevent severe outcomes of COVID-19 infection?
 - Is it to prevent disruption education, long term effects of COVID-19 infection?
 - Is it to minimise inequalities and promote mental health?

7. They looked at wider public health benefits and risks of universal vaccination in this age group to determine if this shifts the risks and benefit either way. Of these, the most important in this age group 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 that influenza vaccination and other immunisations of children and young people are well-established, important, and that the annual flu vaccine deployment programme commences imminently. The UK CMOs, in common with the clinical and wider public health community, consider education one of the most important drivers of improved public health and mental health, and have laid this out in their advice to parents and teachers in a previous joint statement.
8. They advise:
- The additional likely benefits of reducing educational disruption, and the consequent reduction in public health harm from educational disruption, on balance provide 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.**
 - If Ministers accept this advice, 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 has accrued internationally. This will not be before the Spring term.
 - In recommending this to Ministers, UK CMOs recognise that the overwhelming benefits of vaccination for adults, where risk-benefit is very strongly in favour of vaccination for almost all groups, are not as clear-cut for children and young people aged 12-15. **Children, young people and their parents will need to understand potential benefits, potential side effects and the balance between them.**
 - If Ministers accept this advice, **issues of consent need to take this much more balanced risk-benefit into account.** UK CMOs recommend that the Royal Colleges and other professional groups are consulted in how best to present the risk-benefit decisions in a way that is accessible to children and young people as well as their parents. A child-centred approach to communication and deployment of the vaccine should be the primary objective.
 - If Ministers accept this advice, it is **essential that children and young people aged 12-15 and their parents are supported in their decisions**, whatever decisions they take, and are not stigmatised either for accepting, or not accepting, the vaccination offer. **Individual choice should be respected.**
9. The CMO's full advice including the information and evidence they considered on the wider health benefits of vaccinating this age range is at Annex 1.

Options for consideration

10. In considering the JCVI and CMO advice, there are two options to consider:

- **Option A** – to agree to offer the vaccine to 12-15 yr olds, provide response and look to firm up plans to operationalise. In doing so, you would recognise that the JCVI's advice was narrow in focus and looked specifically at the individual health benefit to the child. The JCVI did find that there was a small benefit to this age range being vaccinated. The CMO have found that there is a wider health benefit – especially in terms of education and keeping children in school. Together, this increases the benefit for these children and tips in favour of vaccinating.
- **Option B** – to not accept the CMO advice and to not offer this healthy children within this age range a vaccine. The decision to vaccinate is still very finely balanced and the benefit of vaccinating is still marginal. However, the Ministers of the other nations have indicated that they will accept the CMO advice and so, Wales will be the only nation not to provide this offer and will need clear rational to break away from a consistent four nations approach. You could also chose to delay the offer until more evidence is provided or you have had additional time to consider.

Recommendation

11. We would **recommend option A** to accept the JCVI advice and to formalise this approach. The other nations have indicated that their Ministers are minded to accept the JCVI advice.

Deployment

12. 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 if you decide to vaccinate in line with option A.
13. Healthy school-aged children 12-15 will primarily receive their COVID-19 vaccination in vaccination centres with some health boards offering through schools.

Financial implications

14. The costs of the Covid vaccine implementation programme will be covered from the Covid response funding allocated to the HSS MEG, BEL 0020. An indicative budget has been agreed at £100m for the year. This will be confirmed at second supplementary budget. It is not expected that this development will significantly increase expected costs. Consideration of the full year financial impact of the

programme, including phase 3 from September onwards, is ongoing and Health Boards report monthly on forecast costs for the full year.

Novel or contentious issues

15. This is a very contentious issue and there are very strong lobby groups on both sides. Anti-vax activity has increased significantly since this age range has been discussed, with schools and parents being targeted. Conversely, we believe the education sector would broadly be in favour of vaccinating to avoid disruption to schools. Behavioural insight tells us that parents are split on this with only 50% of parents likely to provide consent.
16. There is also some controversy around consent with misinformation outlets suggesting parents will not be asked for consent. This is not true. The NHS have had tried and tested systems of consent in place for many years and this will continue with all children and young people under 16yrs.

Legal issues, powers & statutory duties

17. The Minister is asked to agree to 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 relating to this cohort. This recommendation is based on advice from the four UK chief medical officers ("CMOs") acting in unison.

The Welsh Minister powers

18. The Welsh Ministers have broad powers to enable this as set out in the NHS (Wales) Act 2006 ('the 2006 Act'). Section 1 of the 2006 Act places a general duty on the Welsh Ministers to provide or secure the provision of services for the purpose of the promotion in Wales of a comprehensive health service, which includes securing improvement in the prevention, diagnosis and treatment of illness. The Welsh Ministers may, under section 2 of the Act, do anything which is calculated to facilitate, or is conducive or incidental to the discharge of such a duty. Additionally, section 3(1)(e) places a duty on the Welsh Ministers to provide throughout Wales, to such an extent as they consider necessary to meet all reasonable requirements, services and facilities for the prevention illness as they consider are appropriate as part of the health service.

JCVI advice

19. The vaccination programme to date has primarily been based on the advice from the JCVI. On the 2 September 2021 the JCVI confirmed that 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 12-15-year-old children. In making this report the JCVI commented that the government may wish to seek further views on the wider societal and educational impacts from the Chief Medical

Officers of the 4 nations, with representation from JCVI in these subsequent discussions.

20. The JCVI is an independent advisory committee with functions in both England and Wales. It was initially established under the NHS (Standing Advisory Committees) Order 1981 (SI 1981/597) as a statutory advisory committee constituted for the purpose of advising on "The provision of vaccination and immunisation services being facilities for the prevention of illness." By virtue of the National Assembly for Wales (Transfer of Functions) Order 1999 and paragraph 1 of Schedule 2 to the NHS (Consequential Provisions) Act 2006 the JCVI is regarded as an advisory committee made under section 189 of the NHS (Wales) Act 2006.
21. The role of an advisory committee under section 189 of the 2006 Act is however to advise the Welsh Ministers on such services provided under the 2006 Act. In England, regulation 2 of the Health Protection (Vaccination) Regulations 2009 ("the 2009 Regulations") impose an obligation on the Secretary of State to ensure implementation of the JCVI recommendations.
22. Wales has committed to following the JCVI advice to date, alongside the other UK nations, and there would need to be good reasons to change that approach. However, there have been instances where there has been different interpretation or operational implementation of the advice. Legally, Welsh Ministers can decide to adopt the JCVI's advice or not, and you may decide, particularly in light of the CMOs advice, that there are justifiable reason for moving away from the JCVI advice this time. While there is no equivalent statutory duty in relation to the Welsh Ministers to that in regulation 2 of the 2009 Regulations any decision could be challenged on public law grounds. Ministers will therefore need to exercise powers reasonably and rationally based on their assessment of the health and scientific advice and evidence as it applies to Wales.

Children's rights and wider considerations

23. The four CMOs have now confirmed that they consider the benefits of reducing educational disruption, and the consequent reduction in public health harm from educational disruption, on balance provide 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.
24. The Welsh Ministers in deciding whether to proceed to offer 12-15 year olds vaccination are required to consider children's rights by virtue of the Rights of Children and Young Persons (Wales) Measure 2011 ('the Measure'). The Measure embeds consideration of the United Nations Convention on the Rights of the Child (UNCRC) and the optional protocols into Welsh law. The main duty required within the Measure, under section 1, requires Ministers to have due regard to the UNCRC.

25. The decision to extend the vaccine programme to 12-15 year olds will require consideration of a number of UNCRC articles, in particular:
- a. Article 3 (best interests of the child)
 - b. Article 5 (parental guidance and a child's evolving capacities) -
 - c. Article 6 (life, survival and development)
 - d. Article 12 (respect for the views of the child)
 - e. Article 24 (health and health services).
26. Article 5 in particular requires government to respect the rights and responsibilities of parents and carers to provide guidance and direction to their child as they grow up, so that they fully enjoy their rights but in a way that recognises the child's increasing capacity to make their own choices.
27. Legal services view is that the proposal, based on the CMO's recommendation, to extend the vaccine programme for children aged 12-15 identified above complies with the UNCRC. This is however subject to appropriate guidance and advice on consent to vaccination being put in place in respect of this cohort. Legal Services note the CMOs' view that if Ministers accept this advice, issues of consent need to take a balanced risk-benefit into account, with a child-centred approach to communication and deployment of the vaccine which ensures children and young people aged 12-15 and their parents are supported in their decisions.
28. Legal services agrees with this and in addition highlights that cohort will include "Gillick competent" children. This term refers to the right of a child under 16 to consent to medical examination and treatment, including immunisation was decided by the House of Lords in *Gillick v West Norfolk and Wisbech AHA* [1986] in which it was held that a child under 16 had the legal competence to consent to medical examination and treatment if they had sufficient maturity and intelligence to understand the nature and implications of that treatment.
29. Guidance to vaccine administrators and health professionals should ensure that before the vaccine is administered to this cohort they must be satisfied that the child understands:
- a. the necessity for vaccination and the reasons for it; and
 - b. the risks, intended benefits and outcomes of the proposed vaccination and alternatives to vaccination, including the option of not having or delaying the vaccination.
- Where the child is unable to understand the above then consent should be obtained from the person who has parental responsibility for the child.

Broader implications for covid-19 restrictions and exemptions

30. UK CMOs advice is for the first dose of Pfizer to be provided 12-15 year olds and that the JCVI should give a view on whether a second doses is to be given to children and young people aged 12-15 once more data on second doses in this age group has accrued internationally.

31. The significance of the vaccination programme as part of the wider consideration of the covid-19 response is currently elevated as vaccination status is increasingly being used as a precursor to accessing certain freedoms. For example, in both the Health Protection (Coronavirus, Restrictions) (No.5) (Wales) Regulations 2020 and the Health Protection (Coronavirus, International Travel) Regulations 2020 there is provision for exemptions from isolation where a person has completed “a course of doses” of an authorised vaccine. A person has completed a course of doses if that person has received the complete course of doses specified in the summary of product characteristics approved as part of the marketing authorisation for the authorised vaccine.
32. This cohort will therefore not be eligible for the exemptions if only offered one dose (unless the marketing authorisation confirms one does as a complete course for 12-15 year olds). Legal Services advise that there will need to be clear information to children and parents regarding the second dose and the implications this has in respect of vaccination status as part of the consent process and risk/benefit analysis.
33. Ministers must also have regard to the duties under section 149 of the Equality Act 2010. While vaccination status is not a protected characteristic under equalities legislation if 12-15 year olds are not offered a second dose this could give rise to challenge on the basis of indirect discrimination based on age. Ministers will therefore need to exercise powers based on their assessment of the health and scientific advice and evidence as it applies to Wales. In coming to conclusions on this issue Ministers need to be clear the evidence which they are weighing in the balance is sufficiently robust to justify the eligibility.
34. Therefore, if the Minister accepts the CMO advice while Legal Services consider the likelihood of successful challenge to currently be low, this is subject to understanding the future decision by the JCVI on whether a second dose is offered and the impact on this cohort in terms of reliance on the current exemptions for fully vaccinated persons in Wales. Officials are therefore advised to keep these matters under close review.

Co-ordination and Communication

35. Officials are attempting to work with the other four nations approach on the timing, choreography, communications around the announcement and publication of any decision and officials are liaising with press team for any further media handling required.
36. We will provide you with lines to take whatever decision you take, and have attached the UKG Q&A at Annex 3.

Annex 1: ASSURANCE AND COPY RECIPIENTS**CLEARANCE TRACKING**

Aspect	Tracking	Yes	No	N/A	Clearance no.
Finance	Financial implications over £50,000?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Cleared by Group Finance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	GH2021/8120
	Cleared by Budget & Government Business Division?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
	Cleared by Local Government Finance?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Legal	Legal issues?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	Cleared by relevant lawyers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Governance	Novel and contentious issues?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
	Cleared by Corporate Governance Centre of Excellence?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

DEPUTY DIRECTOR, STATEMENT OF ASSURANCE

In clearing this MA, I confirm that I, Claire Rowlands have quality assured this advice, ensuring it is provided on the basis of evidence, accurately presents the options and facts and I am accountable for the recommendations made

I am satisfied that the recommended decision or action, if agreed, would be lawful, affordable and comply with all relevant statutory obligations. Welsh Government policy priorities and cross portfolio implications have been fully considered in line with delivery of the government objectives.

I have fully considered the statement of assurance contained in the MA guidance to ensure all relevant considerations have been taken into account and that the actions and decisions take account of regularity, propriety and value for money.

COPY LIST

All mandatory copy recipients (as indicated in the guidance). Additional copy recipients specifically interested in this advice:

Andrew Goodall	Frank Atherton	Claire Rowlands
Gill Richardson	Chris Jones	PS Minister for Finance
HSS Finance	PS First Minister	Name Redacted
Sarah Wakeling	Clare Jenkins	Mitchell Theaker
Name Redacted	Bon Westcott	Andrew Evans
Matthew Jenkins	Elin Gwynedd	Name Redacted
Name Redacted	Marion Lyons	Alex Slade
Name Redacted	Name Redacted	Kate Edmunds
Ruth Meadows	Name Redacted	Name Redacted
	PS Minister for Education	Owain Lloyd

Annex 1 - UK CMOs letter on universal vaccination of children and young people aged 12-15 years against COVID-19

Annex 2 – CMO papers attached in email & in MA folder:

Annex 2 A - JCVI statement on COVID-19 vaccination of children aged 12 to 15 years. Update 2 Sep 2021

Annex 2 B- Terms of Reference for UK CMO advice on universal vaccination of children and young people aged 12-15 years against COVID-19

Annex 2 C- Key published inputs

Annex 2 D- A statement from the UK Chief Medical Officers on schools and childcare reopening

Annex 3 - UKG Q&A