Immunisation Clinical Advice Response Service 17/09/21

For any COVID-19 vaccination related queries or to escalate an incident please contact: england.swicars@nhs.net

Please note that since Monday 2nd August CARS has now become ICARS and will operate from 9am - 5pm Monday to Friday.

PLEASE SHARE WITH ALL RELEVANT STAFF INVOLVED WITH THE VACCINATION PROGRAMME

Contents:

Mixing of Pfizer Vaccine from Different Vials – Further Clarification

As first highlighted last week, please find below further clarification regarding mixing of Pfizer vaccine:

Not only does the Specialist Pharmacy Service Standard Operating Procedure for the preparation of Pfizer vaccine (PVH3) prohibit the mixing of vaccines from different vials, but more importantly the licence SPC and reg 174 conditions are both 100% clear. The licence SPC states the following:

Preparation of individual 0.3 mL doses of Comirnaty

- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted. Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
- Withdraw 0.3 mL dose of Comirnaty. Low dead volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If

standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- **If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.**
- Discard any unused vaccine within 6 hours after dilution

JCVI Statement Regarding a COVID-19 Booster Vaccine Programme for Winter 2021 to 2022

Please read the full statement here

Introduction

The Joint Committee on Vaccination and Immunisation (JCVI) has been asked by the Secretary of State for Health and Social Care to consider the options for and timing of a booster programme to revaccinate adults in order to reduce mortality, morbidity and hospitalisations from COVID-19 over the 2021 to 2022 winter period and through 2022, as well as to minimise the COVID-19 case infection rate and the chance of new variants emerging. With increasing levels of social mixing and close social contact, it is expected that during winter 2021 to 2022 SARS-CoV2 will co-circulate alongside other respiratory viruses, including seasonal influenza virus. Seasonal influenza and SARS-CoV-2 viruses have the potential to add substantially to the 'winter pressures' usually faced by the NHS, particularly if infection waves from both viruses coincide. The timing and magnitude of potential influenza and SARS-CoV2 infection waves for winter 2021 to 2022 are currently unknown.

In JCVI's view, the primary objective of a 2021 COVID-19 booster programme is to maintain protection against severe COVID-19 disease, specifically hospitalisation and deaths, over winter 2021 to 2022. This is exceptional advice aimed at maintaining protection in those most vulnerable, and to protect the NHS. This advice is based on evidence from a number of sources, including UK data on the duration of vaccine-induced protection against severe COVID-19. As not enough time has passed to enable a clear understanding of the level of protection 6 months after completion of the primary vaccine course in all persons, extrapolation of some data has been required.

Taking a precautionary position, JCVI considers that on balance, it is preferable to ensure protection is maintained at a high level throughout the winter months in adults who are more vulnerable to severe COVID-19, rather than implement a booster programme too late to prevent large increases of severe COVID-19 in previously double vaccinated individuals.

At present, it is not known whether recurrent boosters will be required in the long term. This advice on booster vaccination therefore only applies to this highly active phase of the pandemic. This programme is timed to maximise the impact of a booster programme on individual protection against severe disease and to protect the NHS during the winter months.

Considerations

JCVI has reviewed the latest epidemiology of COVID-19 in the UK [footnote 1], mathematical modelling [footnote 2], [footnote 3], data on vaccine safety [footnote 4], [footnote 5] and vaccine effectiveness [footnote 6], [footnote 7], and data from trials undertaken to understand the

immunological impact of booster vaccination [footnote 8], [footnote 9]. Operational and vaccine supply constraints have also been taken into consideration.

The COVID-19 vaccination programme has progressed at pace since December 2020. Early in the programme, the decision was taken to offer the second vaccine dose of the primary schedule after an extended interval for both the COVID-19 Pfizer-BioNTech (BNT162b2/ Comirnaty®) vaccine and the AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine.[footnote 10] The extended second dose interval has been demonstrated to generate a better vaccine immune response which may, in turn, contribute towards greater duration of protection[footnote 11], [footnote 12], [footnote 13] Despite this, recent UK data show early signs of a fall in the levels of protection most evident amongst older individuals who completed their primary vaccine course a longer time ago.[footnote 6]

Data from the COV-BOOST trial indicate that booster doses of COVID-19 vaccines are generally well tolerated and provide a substantial increase in vaccine-induced immune responses.[footnote 8]. In particular, mRNA vaccines provide a strong booster effect, regardless of whether the primary course was with the Pfizer-BioNTech (BNT162b2/ Comirnaty®) or the AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine. These results are consistent with those from other studies that examined the effect of half dose (50µg) Moderna (mRNA-1273/Spikevax®) vaccine following primary courses of full or half doses of Moderna mRNA-1273 vaccination.[footnote 14] A half dose (50µg) of Moderna (mRNA-1273/Spikevax®) vaccine given as a booster was found to cause a similar level of local and systemic reactions to vaccination (injection site pain and headache) compared to a full dose of Moderna (mRNA-1273/Spikevax®) given as a second dose. Data from the ComFluCOV trial indicate that coadministration of influenza and COVID-19 vaccines is generally well tolerated with no diminution of vaccine-induced immune responses to either vaccine.[footnote 9]

Advice

JCVI advises that for the 2021 COVID-19 booster vaccine programme individuals who received vaccination in Phase 1 of the COVID-19 vaccination programme (priority groups 1 to 9) should be offered a third dose COVID-19 booster vaccine. This includes:

- those living in residential care homes for older adults
- all adults aged 50 years or over
- frontline health and social care workers
- all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19 (as set out in the green book), and adult carers
- adult household contacts (aged 16 or over) of immunosuppressed individuals

As most younger adults will only have received their second COVID-19 vaccine dose in late summer or early autumn, the benefits of booster vaccination in this group will be considered at a later time when more information is available. In general, younger, healthy individuals may be expected to generate stronger vaccine-induced immune responses from primary course vaccination compared to older individuals. Pending further evidence otherwise, booster doses in this population may not be required in the near term.

JCVI will review data as they emerge and consider further advice at the appropriate time on booster vaccinations in younger adult age groups, children aged 12 to16 years with underlying health conditions, and women who are pregnant.

Timing of booster vaccination

JCVI advises that the booster vaccine dose is offered no earlier than 6 months after completion of the primary vaccine course, and that the booster programme should be deployed in the same order as during Phase 1, with operational flexibility exercised where appropriate to maximise delivery. Persons vaccinated early during Phase 1 will have completed their primary course approximately 6 months ago. Therefore, it would be appropriate for the booster vaccine programme to begin in September 2021, as soon as is operationally practicable.

Vaccine product for booster vaccination

After reviewing data on booster responses from different combinations of COVID-19 vaccines, JCVI advises a preference for the Pfizer-BioNTech (BNT162b2/ Comirnaty®) vaccine to be offered as the third booster dose irrespective of which product was used in the primary schedule. There is good evidence that the Pfizer-BioNTech (BNT162b2/ Comirnaty®) vaccine is well tolerated as a third dose and will provide a strong booster response. Alternatively, individuals may be offered a half dose (50µg) of the Moderna (mRNA-1273/Spikevax®) vaccine, which should be well tolerated and is also likely to provide a strong booster response. A half dose (50µg) of Moderna (mRNA-1273/Spikevax®) vaccine is advised over a full dose due to the levels of reactogenicity seen following boosting with a full dose within the COV-BOOST trial. Where mRNA vaccines cannot be offered e.g. due to contraindication, vaccination with the AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine may be considered for those who received AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine in the primary course (please refer to the green book for further details)
Other considerations

This advice on booster vaccination is distinct from, and does not supersede, recent advice from JCVI regarding a third primary vaccine dose for persons who are severely immunosuppressed. JCVI will review at a later date whether such persons require a further booster dose following completion of their 3-dose primary vaccine course.
It is not the intention of JCVI that the 2021 COVID-19 booster vaccine programme should disrupt or delay deployment of the annual influenza vaccination programme. Both of these programmes are important for individual and public health, especially over winter 2021 to 2022. Where operationally expedient, COVID-19 and influenza vaccines may be co-administered.

Immediate Action Required for Phase 3 Booster Vaccinations

Please read the full letter here

Dear colleagues

Thank you for the preparations you have undertaken to date to deliver vaccinations this autumn/winter. The Joint Committee on Vaccination and Immunisation (JCVI) have now published their advice on booster vaccinations. This letter sets out the actions we are now asking you to take immediately to begin administering booster doses as soon as possible.

The guidance states:

“JCVI advises that for the 2021 COVID-19 booster vaccine programme individuals who received vaccination in Phase 1 of the COVID-19 vaccination programme (priority groups 1 to 9) should be offered a third dose COVID-19 booster vaccine. This includes:

• those living in residential care homes for older adults
• all adults aged 50 years or over
• frontline health and social care workers
• all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19 (as set out in the green book), and adult carers
• adult household contacts of immunosuppressed individuals"

To support Phase 3 delivery, Public Health England is updating the Patient Group Directive (PGD) and the National Protocol. We expect the PGD to be updated by 21 September and the National Protocol to follow shortly after. Until these have been updated, only sites meeting the prescribing requirements for working under a Patient Specific Direction (PSD) should start to administer booster vaccines. This means sites require a prescriber on-site to administer booster vaccines until the PGD is available, and full capacity may not be achievable until the National Protocol is available. Skipton House 80 London Road London SE1 6LH 15 September 2021Classification: Official Publication approval reference: C1410 2 We will also issue communications materials and leaflets to all vaccination sites and there will be a national communications campaign to support demand and uptake throughout the autumn/winter period.

ACTIONS NOW REQUIRED

For immediate action by all sites offering COVID-19 vaccination services in Phase 3 All sites should now take the following actions to vaccinate in line with the updated JCVI guidance.

1. Overall readiness: sites should make preparations to start vaccinating as soon as possible. This includes ensuring that contractual requirements are in place (see below for Delivery Model specific requirements), and your estates, supplies and IT are all in line with the Phase 3 standard operating procedures, which will be updated this week. You should also roster staff to meet the capacity requirements once your Phase 3 vaccine supply date is confirmed.

2. Managing capacity and booking vaccination appointments: "the JCVI advises that the booster vaccine dose is offered no earlier than six months after completion of the primary vaccine course, and that the booster programme should be deployed in the same order as during Phase 1, with operational flexibility exercised where appropriate to maximise delivery." NBS will therefore be opened to individuals from the date they become eligible and invite eligible individuals accordingly in that order. Local Vaccination Sites should consider prioritising those who are most at risk and those with the longest interval since the 2nd dose of their primary course through Local Booking Systems (in addition, further detail is below on prioritising older age care homes for PCNs).

In preparation for Phase 3, sites should upload their calendars onto the National Booking System, where applicable, with your available capacity for at least 4 weeks from 20 September, subject to site readiness confirmations as set out below. Please ensure you have uploaded your available capacity by midday on Thursday 16 September. For those using Local Booking Systems you should begin inviting individuals to book their vaccine after the below requirements are met.

Site leads will need to do the following before uploading capacity to the National Booking System or inviting individuals for vaccination locally:

ensure that the site meets prescribing requirements (particularly ahead of the PGD and National Protocol being updated), as well as clinical and contractual arrangements

log into Foundry to confirm your vaccine supply delivery date and volumes (see below), and that your capacity reflects this and any locally held stock. Sites should be assured that we are not supply-constrained and should not constrain capacity due to concerns about supply

confirm that the site is assured to administer Pfizer, before Moderna half doses go live.

It is expected that we will open the National Booking System for bookings and issue first national invitations on Monday 20 September. We will work with regions and systems on the volumes of invitations issued through NBS based on available capacity and regions should consider how they could make best use of capacity in advance of national invitations being issued to individuals (e.g. directing health and social care workers to local sites).

3. Vaccine type: the JCVI 'advises a preference for the Pfizer-BioNTech (BNT162b2/ Comirnaty®) vaccine to be offered as the third booster dose irrespective of which product was used in the primary schedule. Alternatively, individuals may be offered a half dose (50µg) of the Moderna (mRNA-1273/Spikevax®) vaccine, which should be well tolerated and is also likely to provide a strong booster response. Where mRNA vaccines cannot be offered e.g. due to contraindication, vaccination with the AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine may be considered for those who received AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine in the primary course (please refer to the Green Book for further details).'

We are taking actions nationally to support administration of a half dose of the Moderna vaccine, including updating Point of Care (POC) systems, updating training and issuing new PIL cards. We will issue further advice on this in due course, but we do not expect to go live with Moderna half doses immediately. Sites should not administer half dose Moderna boosters until instructed to do so. In the meantime, systems should begin administering booster vaccinations with Pfizer as advised by the JCVI and consider how to ensure there are no gaps in delivery in areas where clinics are Moderna only.

4. Vaccine supply: Local Vaccination Sites are required to log in to Foundry to order vaccine supply through the Ordering Platform. All sites will need to have access to Foundry. For further information on how to use the ordering platform, including training and support, please visit the Ordering Platform Training Page on NHS Futures here. Vaccination Centres and Hospital Hubs will order supply through Immform as usual.

5. Recording booster vaccinations: Point of Care (POC) systems have been updated to provide functionality to record booster vaccinations. These must be marked as a "Booster" in your POC systems. Please do not use the 1st or 2nd dose fields as individuals receiving a booster vaccination will have already received their 1st and 2nd doses.

6. Co-administration of COVID-19 and influenza seasonal vaccines: the JCVI guidance states that "where operationally expedient, COVID-19 and influenza vaccines may be co-administered". Therefore, systems should consider co-administration wherever eligibility for both programmes, supply and regulation allow. In particular, systems should seek to co-administer in any instances where it improves patient Classification: Official Publication approval reference: C1410 4 experience and uptake of both vaccines, reduces administrative burdens on services or to reduce health inequalities (eg in HHs, residential care homes and roving models). This will be supported by the Phase 3 Enhanced Service specification for general practice, and the Collaboration Agreement, which will be updated to reflect the JCVI

guidance, supporting practices working as part of a PCN grouping in using their supply of seasonal influenza vaccine at COVID-19 vaccine designated sites (eg at joint clinics). The updated Community pharmacy Local Enhanced Service Specification – phase 3 coronavirus vaccination (the LES) will also be updated to support coadministration where eligibility for both programmes, supply, and regulation allow.

The JCVI have advised that "the COVID-19 booster vaccine programme should [not] disrupt or delay deployment of the annual influenza vaccination programme". Therefore, it is important individuals are offered their COVID-19 and influenza vaccine as soon as they are eligible, rather than delaying for the purpose of co-administration. We recognise there will be some instances where a short delay will ensure that more individuals receive both vaccines, for example in care homes, and sites should use their discretion to maximise these opportunities. Providers should take every opportunity to promote the uptake of both vaccination programmes, including booking individuals in for their influenza vaccine in instances where co-administration cannot realistically be done (taking into account patient choice where eligible patients wish to receive their vaccinations at separate appointments). Vaccination sites should also use appointments as an opportunity for other health promotion activity, 'Making Every Contact Count' where practical and appropriate, as well as for co-promotion of flu and COVID-19 vaccine.

For all PCN-led local vaccination services (LVS)

- This letter constitutes formal notification of the commencement date to GP practices under paragraph 9.1 of the Enhanced Service specification for Phase 3. The Enhanced Service specification is being updated to reflect the JCVI recommendation. Once updated, practices may start vaccinating sooner than the 25 September (i.e. 10 days from this notification) if they are ready, with written agreement with the local commissioner (which can be via email).

- PCN led LVS should prioritise care homes for older adult care home residents and care home staff. We are asking that all eligible patients in this cohort be offered a vaccination by 1 November 2021, and therefore delivery plans should be designed to meet this target. As in previous phases, an additional supplement of £10 per dose on top of the item of service fee for all vaccines delivered in a care home setting will apply.

- We have previously announced further funding temporarily for PCN Clinical Director support for April 2021 to September 2021 (letter of 11 March 2021 and letter of 17 June 2021). We are now able to confirm this funding will be extended to be available from October 2021 to March 2022 though at a lower level than previous quarters to ensure it is affordable within the overall funding envelope for the vaccination programme. In recognition of the valuable work carried out by PCNs, from October 2021, this funding will be equivalent to an increase in Clinical Director time per PCN Classification: Official Publication approval reference: C1410 5 from 0.25WTE to 0.75 WTE for this period. The payment is to support the leadership and management of the COVID-19 support. The PCN Finance and Payments Guidance 2021/22 here will shortly be updated to reflect this.

For all Hospital Hubs / LVSs vaccinating health and social care staff

- Vaccination of health and social care workers can begin immediately in Hospital Hubs. This should be co-administered with flu vaccine wherever possible.
- Hospital hubs will be the default provider for vaccination of eligible trust health care workers. Local systems may have developed alternative local arrangements with

vaccination centres, or GP and Community Pharmacy-run local vaccination centres. Trust HR directors will be responsible for overseeing the uptake of HCW vaccinations in their organisations.

- Regional Teams will complete the reactivation and readiness processes for each Hospital Hub or Hospital Hub Plus site prior to Phase 3 commencement. Hospital Hubs and Hospital Hub Plus sites will not receive allocation of vaccine until Foundry reflects that readiness checks have been completed and signed off by regional teams.
- As in the earlier phases of the programme it is expected that Hospital Hubs / Plus will also support opportunistic vaccination of inpatients and outpatients who require a booster vaccination as per the guidance from the JCVI. For all community pharmacy-led LVSs
- The Local Enhanced Service specification for Community Pharmacies is being updated to reflect the JCVI recommendation and this will be issued by regional teams shortly.
- Until the PGD and National Protocol have been updated, only Community Pharmacies with a prescriber on-site are able to administer booster dose vaccinations.
- Prior to commencing vaccinations under the Community Pharmacy Local Enhanced Service COVID-19 vaccination programme: phase 3 2021/22 agreement, Community Pharmacy sites must have completed all the tasks in the "Ready to Vaccinate Checklist", included at Annex B, in their Confirmation Letter and Mobilisation Guide, have signed the LES and returned a copy to their regional team, and had confirmation from the local commissioner of the service commencement date.
- Regional Teams will complete the Phase 3 Site Readiness Checklist on Foundry for each Community Pharmacy-led site. Both new and existing sites will need to have this approval prior to service commencement. Community Pharmacy-led sites will not receive delivery of vaccine until Foundry reflects that readiness checks have been completed. Sites are responsible for checking their readiness status on Foundry. Sites can technically raise an order for phase 3 vaccine prior to being marked as ready on Foundry by the regional team but vaccine will not be distributed unless they are confirmed as site ready on Foundry at the time of their ordering cut off (this can be viewed on the ordering platform).
- Sites can commence booster vaccines ahead of NBS opening to focus on health and social care workers via walk-ins/local bookings. In order to do this they must still have signed the Community Pharmacy Local Enhanced Service Specification – phase 3 coronavirus vaccination (the LES), been approved on Foundry as site ready for phase Classification: Official Publication approval reference: C1410 6 3 by the regional team and meet the current legal requirements (PSD until PGD or National Protocol in place).

For all Vaccination Centres

- As above, until the PGD and National Protocol have been updated, only Vaccination Centres with a prescriber on-site are able to administer booster dose vaccinations. Site leads are required to have arrangements at arrival in place to identify patients who are attending for a booster vaccination, and in the case the site does not meet the prescribing requirements yet, site leads need to develop local processes to direct people to their local PCN-led vaccination site or Hospital Hub, or support booking of a suitable appointment via the National Booking System.

Please continue to do everything possible to minimise any inequalities in vaccine uptake during Phase 3 and consider how you can best work with CCG, local authority and community partners to reach eligible individuals, with adequate focus on those in underserved communities from the outset of the programme.

The booster campaign will be delivered alongside existing requirements to administer an evergreen offer to those who have not yet had their first or second dose, vaccinations for 12-15 year olds (including those who are at higher risk) and third doses as part of the primary vaccination course for immunosuppressed individuals.

We are holding a webinar tomorrow, Thursday 16 September, from 4pm to 5pm to set out the next steps. Please register by 2.30pm tomorrow and further details will be provided then.

We remain hugely grateful to you for all the work you are doing to deliver the vaccination programme, particularly over the Winter period, and will continue to work closely with regions and systems to support Phase 3 delivery.

Professor Sir Keith Willett
SRO Vaccine Deployment
NHS England and NHS Improvement

Dr Nikita Kanani
Medical Director for Primary Care
NHS England and NHS Improvement

Universal vaccination of children and young people aged 12 to 15 years against COVID-19

Letter from the UK Chief Medical Officers to the UK Health Ministers on COVID-19 vaccination of 12 to 15 year olds.

Please read in full at the following link: Universal vaccination of children and young people aged 12 to 15 years against COVID-19 - GOV.UK (www.gov.uk)

3 September 2021

Dear Secretary of State, Cabinet Secretary and ministers,

Background

The Joint Committee on Vaccination and Immunisation (JCVI) in their advice to you on 2 September 2021 on this subject said:

"Overall, the committee is of the opinion that the benefits from vaccination are marginally greater than the potential known harms… but acknowledges that 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…. JCVI is constituted with expertise to allow consideration of the 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. 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."

Their full advice to you is appended in JCVI statement, September 2021: COVID-19 vaccination of children aged 12 to 15 years.
You accepted this recommendation from JCVI, and wrote to us on 2 September 2021 stating "We agree with the approach suggested by JCVI, and so we are writing to request that you take forward work (drawing on experts as you see fit) to consider the matter from a broader perspective, as suggested by the JCVI."

The terms of reference (ToR) of this request, which the UK CMOs agreed, can be found in Terms of reference for UK CMO advice on universal vaccination of children and young people aged 12 to 15 years against COVID-19

In doing so we have been fortunate to have been informed by the independent expertise of leaders of the clinical and public health profession from across the UK. This has included Presidents and Chairs or their representative of:

- Royal College of Paediatrics and Child Health
- Royal College of General Practice
- Royal College of Psychiatry
- Faculty of Public Health
- Academy of Medical Royal Colleges representing all the other Royal Colleges and Faculties
- Association of Directors of Public Health
- Regional Directors of Public Health
- national public health specialists
- experts in data and modelling

We are very grateful to them for taking considerable time and effort to consult their own colleagues in all 4 nations at short notice to get a comprehensive view of the balance of informed medical opinion and experience across the UK.

In addition, we have examined data from the Office for National Statistics as well as published data on the impact of COVID-19 on education, and other relevant published sources. We attach key published inputs in Key published inputs to the UK CMOs advice on universal vaccination of children and young people aged 12 to 15 years against COVID-19.

The UK's independent regulator of medicines and vaccines the Medicines and Healthcare products Regulatory Agency (MHRA) is in law the appropriate body to determine whether, based on risk-benefit grounds, a vaccine is safe and effective to use and so grant a licence. They have done so for children and young people aged over 12 years for two vaccines against COVID-19, those manufactured by Pfizer and Moderna. Their assessment is that benefits exceed risks on an individual basis. We take their independent opinion as read. The MHRA position on mRNA vaccines is similar to the relevant regulatory approvals granted in the same age groups in multiple other jurisdictions including but not limited to the USA, the European Union, and Canada.

The independent JCVI is the proper body to give advice on how to deploy a vaccine which has a prior favourable risk-benefit decision and authorisation from MHRA including whether it has a sufficiently large benefit to be worth deploying on a larger, population scale. Like MHRA they

consider the benefits of vaccination in this age group exceed the risks (i.e. it is better to be vaccinated than not vaccinated in this age group). They balanced the risk of COVID-19 against the risks of vaccination, including myocarditis. When forming its advice, the JCVI considered vaccine use according to clinical risk groups, thus identifying different groups according to their potential to benefit from vaccination.

For 12 to 15 year olds who do not have underlying health conditions that place them at higher risk from severe COVID-19, the JCVI considered that the size of both the risk and the benefit are at an individual level very small, and the overall advantage for vaccination, whilst present, is therefore not sufficiently large to recommend universal vaccination on their usual criteria. They deemed the extent to which vaccination might mitigate the impacts of COVID-19 on education was beyond the usual remit of the JCVI. They recognised however that given the substantial scale of the impact of COVID-19 on all children and young people, which goes beyond normal clinical benefit and risk, wider issues could, exceptionally, be relevant hence their suggestion to consult UK CMOs.

The JCVI have already recommended that children and young people aged 12 to 17 with specific underlying health conditions, and children and young people who are aged 12 years and over who are household contacts of persons who are immunocompromised are offered two doses of a vaccine, normally Pfizer BioNTech BNT162b2. They have recommended all young people 16 to 17 are offered an initial first dose of vaccine.

The UK has benefited from having data from the USA, Canada and Israel, which have already offered vaccines universally to children and young people aged 12 to 15.

The UK CMOs start from the position that the MHRA and JCVI set out on individual benefit-risk calculations for this age group, and have not revisited this. We accept that at an individual level benefit exceeds risk but this advantage is small, and we have taken the JCVI figures as the UK current position on this question.

The Chair of the JCVI Prof. Lim has been a member of our group to ensure that there is no duplication of effort or conflict between the views of UK CMOs and the JCVI. We have been fortunate to have been joined also by the lead Deputy Chief Medical Officers for vaccines Prof. Van Tam (England), Prof. Steedman (Scotland) and Dr. Chada (Northern Ireland) and the DHSC Chief Scientific Adviser, Prof. Chappell. The final advice is that of the Chief Medical Officers, but informed by independent senior clinical and public health input from across the UK.

UK CMOs have decided in their ToR that we will only consider benefits and disbenefits to those aged 12 to 15 from vaccinating this age group, including indirect benefits. Whilst there may be benefits to other age groups, these have not been considered in our advice below.

Issues of vaccine supply were not factors considered in decision making.

The UK CMOs are aware of the extensive range of non-clinical views but this UK CMOs advice is purely clinical and public health derived and has not taken issues outside their clinical and public health remit into account. There is a subsequent political process where wider societal issues may be considered by ministers in deciding how they respond to this advice.

Advice

All drugs, vaccines and surgical procedures have both risks and benefits. If the risks exceed benefits the drug, vaccine or procedure should not be advised, and a drug or vaccine will not be authorised by MHRA. If benefits exceed risks then medical practitioners may advise the drug or vaccine, but the strength of their advice will depend on the degree of benefit over risk.

At an individual level, the view of the MHRA, the JCVI and international regulators is that there is an advantage to someone aged 12 to 15 of being vaccinated over being unvaccinated. The COVID-19 Delta variant is highly infectious and very common, so the great majority of the unvaccinated will get COVID-19. In those aged 12 to 15, COVID-19 rarely, but occasionally, leads to serious illness, hospitalisation and even less commonly death. The risks of vaccination (mainly myocarditis) are also very rare. The absolute advantage to being vaccinated in this age group is therefore small ('marginal') in the view of the JCVI. On its own the view of the JCVI is that this advantage, whilst present, is insufficient to justify a universal offer in this age group. Accepting this advice, UK CMOs looked at wider public health benefits and risks of universal vaccination in this age group to determine if this shifts the risk-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. 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 had on the welfare and mental health of many children and young people. This is despite remarkable efforts by parents and teachers to maintain education in the face of disruption.

The negative impact has been especially great in areas of relative deprivation which have been particularly badly affected by COVID-19. The effects of missed or disrupted education are even more apparent and enduring in these areas. 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.

Whilst full closures of schools due to lockdowns is much less likely to be necessary in the next stages of the COVID-19 epidemic, UK CMOs expect the epidemic to continue to be prolonged and unpredictable. Local surges of infection, including in schools, should be anticipated for some time. Where they occur, they are likely to be disruptive.

Every effort should be taken to minimise school disruption in policy decisions and local actions. Vaccination, if deployed, should only be seen as an adjunct to other actions to maintain children and young people in secondary school and minimise further education disruption and therefore medium and longer term public health harm.

On balance however, UK CMOs judge that it is likely vaccination will help reduce transmission of COVID-19 in schools which are attended by children and young people aged 12 to 15 years. COVID-19 is a disease which can be very effectively transmitted by mass spreading events, especially with Delta variant. Having a significant proportion of pupils vaccinated is likely to reduce the probability of such events which are likely to cause local outbreaks in, or

associated with, schools. They will also reduce the chance an individual child gets COVID-19. This means vaccination is likely to reduce (but not eliminate) education disruption.

Set against this there are operational risks that COVID-19 vaccination could interfere with other, important, vaccination programmes in schools including flu vaccines.

Overall however the view of the UK CMOs is that 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 to 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 to 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 to 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 to 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.

Chief Medical Officer for England Prof. Christopher Whitty
Chief Medical Officer for Northern Ireland Sir Michael McBride
Chief Medical Officer for Scotland Dr. Gregor Smith
Chief Medical Officer for Wales Dr. Frank Atherton

Vaccination of Healthy Children and Young People Aged 12 to 15

The full letter can be read at the link below:

Coronavirus » Vaccination of healthy children and young people aged 12 to 15 (england.nhs.uk)

Dear colleagues

Following the Government's acceptance of the UK CMOs' recommendation to extend the offer of universal vaccination with a first dose of the Pfizer vaccine to all children and young people

aged 12 to 15 (who are not already covered by existing JCVI advice), below sets out the actions that need to be taken to ensure the timely operationalisation of this work.

We are grateful for the significant work that has already been undertaken across systems to prepare for the Government's decision.

This is a new delivery model for the programme, and systems should commence formal engagement with their local school aged immunisation service (SAIS) providers to operationalise delivery of COVID-19 vaccinations in school settings and make specific provision available for those children aged 12-15 who are not in mainstream education.

Systems will ensure that all existing SAIS providers are offered the opportunity to provide the COVID-19 vaccination service and should be supported to work with all local providers to bolster and supplement capacity using existing staff sharing arrangements through lead employers or sub-contracting with partners, if required.

Beyond outreach to those not in mainstream education, any system planning to vaccinate children in a setting outside of a school more widely should only do this by exception and with agreement of the NHS Regional Director. The children's service will be delivered alongside existing requirements of the National Vaccines Skipton House 80 London Road London SE1 6LH 15 September 20211 Programme and in agreeing exceptions systems must consider the impact on wider capacity for vaccinations.

ACTIONS NOW REQUIRED

For immediate action by systems

Systems should now take the following actions to ensure that all children aged 12 (on or before the date of vaccination) to 15, in line with the UK CMOs' advice, are provided with consenting materials, screened and have received an invitation/ date to be vaccinated before the half-term break.

Only those existing vaccination sites who have been sub-contracted or reached agreement with their NHS England regional team should commence vaccinating this cohort. This includes PCNs.

Our objective is to vaccinate children as quickly as is safe and practical, with the majority of school visits completed and vaccinations administered before October half term. Recognising there is a 5 week period from go-live to half term, it is acknowledged some school visits may fall after the half term break. In these instances, the offer process, and the date of vaccination, should be confirmed before the half term break.

As per previous advice and instruction, systems are reminded of the importance of timely vaccination of at risk 12-15 year olds on a two dose schedule.

1. Overall readiness

Systems should make preparations to commence the programme no later than Wednesday 22 September working collaboratively with schools, Directors of Public Health and Local Authorities to ensure a high quality service is delivered at pace to children with minimal disruption to their education.

Providers should review the Service Specification and note the processes for infection control, medicines management and consent.

The service specification covers the primary offer of a vaccination to all 12-15s (including all children who are 12 on or before the date of vaccination). A follow-up offer will be required to ensure that those turning 12 after this date, those who are unable to take up the offer due to absence from school on the day of vaccination and/or a positive COVID result within 28 days of the vaccination date in school, as well as those who subsequently change their minds or take longer to reach a decision about taking up the vaccine offer, are able to access the vaccine.

Further guidance will follow on the expectations of a secondary offer, and the evergreen offer for those turning 12. It is anticipated that this will be delivered out-of-school (to minimise any further disruption to education and other immunisation programmes). The CMOs have noted the importance of influenza vaccination and other immunisations of children and young people. Systems will be required to consider the equalities impact of any secondary offer, particularly in relation to those 2 schools that are going early in the deployment programme where consent and uptake rates may be lower.

Vaccination of at risk 12-15s and 16-17 year olds should continue at pace in the wider vaccine delivery network. It is anticipated that systems will be able to utilise school aged immunisation services to enhance the vaccination offer to clinically vulnerable 12-15 year olds and 16-17 year olds in schools who have not yet taken up a first dose. A separate service specification will follow for these groups, in order that the primary service specification is not delayed.

2. Commence the consent and invitation process

Consenting information leaflets will be made available imminently. Providers should immediately liaise with school settings to make arrangements to send out information and consent details to parents/carers of all children and young people aged 12-15 not already covered by existing JCVI advice and to agree date(s) for vaccination. Systems will need to have processes in place to exclude children that have already received a first dose under previous JCVI advice.

Providers should ensure that their consent processes follows best practice outlined in the Green Book.

Any Provider that opts to enter into a subcontracting arrangement with additional Providers will need to ensure that consent forms include the name(s) of all Providers that will be participating in the care pathway – specific guidance can be found in the Service Specification.

3. Workforce

System lead employers should contact their local SAIS providers to discuss workforce requirements and support the deployment of additional staff to ensure there are additionality and resilience arrangements in place.

The workforce considerations for vaccinating children aged 12 – 18 years old shared on 23 July 2021 include the clinical red lines, training standards and competencies that any individual vaccinating a child or young person should have achieved. This remains unchanged and lead employers should ensure they continue to apply this guidance and train as many people as possible to ensure maximum coverage of staffing.

4. Co-administration

Systems may find it beneficial operationally to co-administer COVID-19 with other routine immunisations including influenza. Guidance on co-administration can be found in the Green Book. **Systems should not delay vaccinations to co-administer**.

5. Patient Group Directive and National Protocol

The PGD will be available on 21 September, in readiness for commencement of vaccinations on 22 September and the National Protocol will follow soon thereafter.

6. Contracting for services

A package of contracting materials will be sent directly to systems via NVOC. This will include a contract specification and Letter of Intent.

We are holding a webinar this Thursday 16 September from 4pm to 5pm to set out the next steps. Please register by 2.30pm this Thursday and further details will be provided then. Thank you in advance for everything you are doing to continue to deliver a world-leading vaccination programme.

Professor Sir Keith Willett
SRO Vaccine Deployment
NHS England and NHS Improvement

Dr Nikita Kanani
Medical Director for Primary Care
NHS England and NHS Improvement

COVID-19 Vaccination Programme for Children and Young People: Guidance for Schools

Please read the guidance at the link below:

COVID-19 vaccination programme for children and young people: guidance for schools - GOV.UK (www.gov.uk)

COVID-19 Response: Autumn and Winter Plan 2021

Please read at the link below.

COVID-19 Response: Autumn and Winter Plan 2021 - GOV.UK (www.gov.uk)

All COVID-19 vaccination queries and incidents should be directed to:
england.swicars@nhs.net