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To:

- All GP practices
- · All community pharmacy-led vaccination sites
- Vaccination centres
- All CCGs
- All directors of public health
- All directors of children's services
- All NHS trust chief executives
- All ICS and STP leads

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- All local authority chief executives
- NHS regional directors
- NHS regional directors of commissioning
- Chairs of ICSs and STPs
- Chairs of NHS trusts and foundation trusts Chairs of ICSs and STPs
- Chairs of NHS trusts and foundation trusts

2 September 2021

Dear colleague

Updated JCVI guidance for vaccinating immunosuppressed individuals with a third primary dose

The Joint Committee on Vaccination and Immunisation (JCVI) <u>has issued updated</u> <u>guidance in relation to COVID-19 vaccinations for individuals aged 12 years and over with severe immunosuppression</u>. This letter sets out the actions we are asking systems to take from today to begin vaccinating this group with a third dose as part of their primary vaccination course by 13 September 2021.

The guidance states:

"At the current time, JCVI advises that a third primary dose be offered to individuals aged 12 years and over with severe immunosuppression in proximity of their first or second COVID-19 vaccine doses in the primary schedule. Severe immunosuppression at the time of vaccination is defined using the guidance [in Annex A] and timings stated below."

"For those aged 18 years and over, JCVI advises a preference for mRNA vaccines for the third primary dose, with the option of the AstraZeneca Vaxzevria vaccine for individuals who have received this vaccine previously where this would facilitate delivery. In exceptional circumstances, persons who received a mRNA COVID-19 vaccine previously may be offered a third primary dose of AstraZeneca Vaxzevria vaccine following a decision by a health professional on a case-by-case, individualised basis. For those aged 12 to 17 years the Pfizer-BNT162b2 vaccine remains the preferred choice, as set out in JCVI advice of 4 August 2021."

"The specialist involved should advise on whether the patient fulfils the eligibility criteria and on the timing of any third primary dose. In general, vaccines administered

during periods of minimum immunosuppression (where possible) are more likely to generate better immune responses. The third primary dose should ideally be given at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies guided by the following principles:

- where possible, the third primary dose should be delayed until 2 weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent
- if not possible, consideration should be given to vaccination during a treatment 'holiday' or at a nadir of immunosuppression between doses of treatment"

It is important to note that JCVI have advised this forms part of the primary vaccination schedule for an individual and therefore further advice will be provided on a booster vaccination in due course for these individuals.

ACTIONS NOW REQUIRED

The vaccination of eligible individuals will require a co-ordinated approach between primary and secondary care to ensure we are able to reach all eligible individuals in this cohort.

Next steps: guidance for secondary care

- We are asking all consultants to identify patients within their care who are in the JCVI's definition as being eligible for a third primary dose and to consider the optimal timing for administering a third dose, based on the JCVI's advice. The full list of eligible individuals is listed in Annex A and a template letter to issue to eligible patients is in Annex B.
- Within this, it is recognised that for some individuals who are on regular, long term immunosuppressive therapy or where the degree of immunosuppression is relatively constant that the specific timing of vaccination is likely to be less important. Such individuals do require vaccination.
- If the individual is receiving care within a hospital that operates as a hospital hub and there is available vaccine supply, we recommend the individual receives the vaccine on site in line with the consultant's recommendation on timing.
- If it is not possible to offer the individual a vaccine on site, consultants should write clear advice to the individual's GP specifying the optimal timing and any interaction with their current treatment (a template letter can be found in Annex C). The individual should then receive their vaccination through a PCN grouping-led site. The Phase 1 & 2 Enhanced Service specification for general practice COVID-19 vaccinations contains provision for sites to follow JCVI guidance on the vaccination requirements, including dose schedule, for different patient groups, and therefore no change to this contractual document is required to enable PCN-groupings to administer a third dose to these patients.
- It is also recommended that individuals are reminded that household contacts of those who are immunosuppressed are advised to be vaccinated. Individuals aged 17 ¾ and over can book via the National Booking System and children aged 12 and over should speak to their registered GP practice, who will then invite them to attend their GP-led Local Vaccination Service. Further details are here for adults and here for children aged 12-15.

Next steps: guidance for PCNs

- In parallel, we are asking all GP practices to identify individuals on their registered list against the eligibility definition provided by the JCVI. This will be supported by provision of searches (we expect these to be available by the end of September), but where practices can identify individuals themselves in advance of this, they should.
- Once these individuals have been identified, practices should offer them a third
 primary dose through their PCN with consideration to the optimal timing and
 interaction with any treatment as set out by the JCVI. A template letter to issue to
 eligible patients is in Annex B. As above, those who are on regular
 immunosuppressive medication or have relatively stable immunosuppression can
 be called for vaccination by PCNs 8 weeks since their second dose.
- Practices that are not delivering the COVID-19 vaccination enhanced service should share a list of eligible patients with their local commissioner so they can arrange for these patients to be offered an appointment at another provider (e.g. another PCN-led vaccination site or Hospital Hub) by 17 September. This request is necessary for the reasons of public interest.

Next steps: guidance for Vaccination Centres and Community Pharmacies

- We are exploring how we could provide individuals with the option of a vaccination with an alternative provider or delivery model where required.
- However, currently vaccination of third primary doses will be covered by the PSD and therefore only those with a prescriber on site will be able to administer third primary doses. We are looking into updating the PGD / national protocol and will issue further advice in due course on how this might work.
- The Community Pharmacy LES 2020/21 (phases 1 & 2) contains provision for sites
 to follow JCVI guidance on the vaccination requirements, including dose schedule,
 for different patient groups, and therefore no change to this contractual document is
 required to enable community pharmacy to administer a third dose to these
 patients.

Recording a third dose in point of care systems

 We are working on a solution to be able to capture third doses in point of care systems and will provide further information to systems w/c 6 September. We expect this solution will be operationalised by 13 September ready to begin vaccinating by then.

Please continue to do everything possible to minimise any inequalities in vaccine uptake when operationalising this guidance and consider how you can best work with CCG, local authority and community partners to reach these individuals. As above, this may also present an opportunity for <u>vaccination of household contacts</u> of the immunosuppressed aged 12 and over and systems should seek to maximise this opportunity. The JCVI updated their <u>advice in July</u> to include children aged 12-15 as household contacts and we ask that systems endeavour to vaccinate this cohort as soon as possible in line with this advice.

Our vaccination programme was designed to be flexible to deliver on JCVI guidance and to protect people from serious illness. Thank you for your continued efforts in delivering a highly successful vaccination programme and your efforts to identify and vaccinate this vulnerable population.

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

Annex A – JCVI list of eligible individuals

- 1. Individuals with primary or acquired immunodeficiency states at the time of vaccination due to conditions including:
- acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who were under treatment or within 12 months of achieving cure
- individuals under follow up for chronic lymphoproliferative disorders including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias (note: this list is not exhaustive)
- immunosuppression due to HIV/AIDS with a current CD4 count of <200 cells/µl for adults or children
- primary or acquired cellular and combined immune deficiencies those with lymphopaenia (<1,000 lymphocytes/ul) or with a functional lymphocyte disorder
- those who had received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the previous 24 months
- those who had received a stem cell transplant more than 24 months ago but had ongoing immunosuppression or graft versus host disease (GVHD)
- persistent agammaglobulinaemia (IgG < 3g/L) due to primary immunodeficiency (for example, common variable immunodeficiency) or secondary to disease/therapy
- 2. Individuals on immunosuppressive or immunomodulating therapy at the time of vaccination including:
- those who were receiving or had received immunosuppressive therapy for a solid organ transplant in the previous 6 months
- those who were receiving or had received in the previous 3 months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but in this case the recipient would be considered immunosuppressed for a 6-month period), T-cell co-stimulation modulators, monoclonal tumour necrosis factor inhibitors (TNFi), soluble TNF receptors, interleukin (IL)-6 receptor inhibitors, IL-17 inhibitors, IL 12/23 inhibitors, IL 23 inhibitors (note: this list is not exhaustive)
- those who were receiving or had received in the previous 6 months immunosuppressive chemotherapy or radiotherapy for any indication
- 3. Individuals with chronic immune-mediated inflammatory disease who were receiving or had received immunosuppressive therapy prior to vaccination including:
- high-dose corticosteroids (equivalent to ≥ 20mg prednisolone per day) for more than 10 days in the previous month
- long-term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months

- non-biological oral immune modulating drugs, such as methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day, 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day in the previous 3 months
- certain combination therapies at individual doses lower than above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months
- 4. Individuals who had received high-dose steroids (equivalent to >40mg prednisolone per day for more than a week) for any reason in the month before vaccination.

Individuals who had received brief immunosuppression (≤40mg prednisolone per day) for an acute episode (for example, asthma / COPD / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination.

Annex B: Template letter to severely immunosuppressed individuals for GP practices and consultants to adapt and issue

Individuals aged 12 and over with severe immunosuppression are now recommended to receive a third primary dose of the COVID-19 vaccine

Dear [name]

We are writing to let you know that you are now eligible for an extra dose of the COVID-19 vaccine in light of the <u>latest advice from the Joint Committee on Vaccination and Immunisation</u> (JCVI). The advice recommends that a third dose is given for individuals aged 12 and over with immunosuppression and you are eligible within this category given your current health condition. This is being advised as a precautionary measure to increase your immunity level and provide a better vaccine response, based on studies and experience with other vaccines. It is part of your primary course of vaccination and is separate to a booster vaccination, which you will likely become eligible for in six months' time, pending further advice.

We recommend you contact your [GP / Consultant] to discuss the optimal timing to receive your vaccination, which must be at least 8 weeks after your second dose. Your [GP or consultant] will advise you how you can book an appointment to receive your third dose, which may be at the hospital where you receive treatment, your local Primary Care Network or at another site they direct you to.

For more information about the coronavirus vaccine, read the leaflet that came with this letter or visit www.nhs.uk/covid-vaccination.

Yours sincerely

[Signatory]

Annex C - Template letter for consultants (to be put on consultant / GP letterhead)

Dear [GP name / to whom it may concern],

I have assessed patient [name] and they meet the criteria set out in the latest JCVI advice on vaccinating individuals aged 12 and over with severe immunosuppression and the Green Book due to [outline of condition].

Therefore, I am recommending that [name] be offered an extra third dose of the COVID-19 vaccine as part of their primary vaccination course.

They should be offered a vaccination between [dates] to ensure optimal interaction with their treatment. If the individual does not receive their vaccination within these dates, you should refer them back to [myself / the practice].

JCVI have advised a preference for mRNA vaccines for the third primary dose, with the option of the AstraZeneca Vaxzevria vaccine for individuals who have received this vaccine previously where this would facilitate delivery.

Please accept this letter as proof of [his/her/their] eligibility status to receive a third dose due to [his/her/their] immunosuppressed status.

Yours sincerely

[Signatory]