From the Chief Medical Officer
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An Roinn Sláinte
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FOR ACTION
Chief Executives HSC Trusts
for onward cascade to Medical Directors

Chief Executive, Public Health Agency and Health and Social Care Board/NIAS *for onward cascade as appropriate*

Assistant Director of Integrated Care
Head of General Medical Services, Health and Social Care Board *for onward cascade to All General Practitioners, GP Locums and Practice Staff*
OOHs Medical Managers

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

ADVICE ON THIRD PRIMARY DOSE FOR COVID-19 VACCINATION

1. The Joint Committee on Vaccination and Immunisation (JCVI) has issued updated guidance in relation to COVID-19 vaccinations for individuals aged 12 years and over with severe immunosuppression, see attached link to JCVI advice - JCVI issues advice on third dose vaccination for severely immunosuppressed - GOV.UK (www.gov.uk)

2. At this current time JCVI advises that a third primary dose be offered to individuals aged 12 year and over with severe immunosuppression in proximity of their first or second COVID-19 vaccine doses in the primary schedule. A definition of severe immunosuppression at the time of vaccination is defined in Annex A.

3. It is essential that these individuals are now identified in order to consider if/when they should receive their third primary dose of a COVID-19 vaccine. 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. The vast majority of individuals are likely to

be identified by their secondary care clinician but some individuals, particularly those at point 4 of Annex A, may only be known by their GP.

4. Trusts should now identify these individuals, contact them and make the necessary arrangements to have them vaccinated in the Trust, ensuring where possible the efficient use of vaccines. A draft letter is attached which Consultants may wish to adapt as necessary and use at Annex B. When issued it should also be cc'd to the patients GP.

5. For those individuals in group 4, Annex A, GPs should identify those patients where they prescribed the high dose steroids and if they are not also currently receiving treatment via secondary care, they should be issued with a letter recommending that they receive a 3rd primary dose via a local community pharmacy using the Moderna vaccine. Draft letters are attached at Annex B and C which GPs may wish to adapt and use.

   Please note, if any of these individuals are aged 12 to 17 years of age they will be unable to receive the Moderna vaccine and therefore these individuals should be referred to their local Trust via the CCG route to be considered for vaccination.

6. 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 aged 40 years or over 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.

7. The decision on the timing of the third primary dose should be undertaken by the specialist involved in the care of the patient. If they consider it necessary, the GP should seek additional advice from a specialist before making a decision on the timing of the 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 be given at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third primary dose should be delayed until two 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.

8. As with current advice in the Green Book (chapter 14a) JCVI has advised that "individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19". Re-vaccination with a 2-dose schedule should be considered 3-6 months post autologous and allogeneic human stem cell transplant or CAR-T therapy. A third primary dose of vaccine should

be administered, at least 8 weeks after the second dose (in line with the advice above).

9. Most individuals whose immunosuppression commenced at least two weeks after the second dose of vaccination do not require a third primary dose at this stage. Alongside those with lower levels of immunosuppression, they are likely to become eligible for a booster dose as part of a routine booster programme from around six months after the second dose, pending further advice.

10. 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

11. We fully appreciate that the programme is becoming ever more complicated but it is essential we all keep up the continued efforts in ensuring the COVID-19 vaccination programme is implemented and that those with severe immunosuppression are able to receive the most appropriate vaccination schedule for them as recommended by JCVI.

Yours sincerely



Prof Sir Michael McBride
Chief Medical Officer

Prof Charlotte McArdle
Chief Nursing Officer

Mrs Cathy Harrison
Chief Pharmaceutical Officer

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This letter is available on the Department of Health website at https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications

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 latest advice from the Joint Committee on Vaccination and Immunisation (JCVI) - JCVI issues advice on third dose vaccination for severely immunosuppressed - GOV.UK (www.gov.uk).

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] on the following telephone no. xxxx to discuss the optimal timing to receive your vaccination, which must be at least 8 weeks after your second dose.

For more information about the coronavirus vaccine, visit the PHA website - www.pha.site/COVID19infomaterials

Please note, if you are aged between70-79 years of age, you will also be eligible to receive the non-live shingles vaccine Shingrix® as you are unable to receive the live vaccine Zostavax®. It is recommended that you also take

up this offer when invited to receive the Shingrix® vaccine by your GP in due course.

Yours sincerely
[Signatory]

cc Patient's GP.

Annex C

Template letter for GPs to issue to allow their patient to receive the vaccine via Community Pharmacy (to be put on GP letterhead)

Dear [to whom it may concern],

I have assessed my 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 a 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]