FAQ on Covid Boosters and Covid Third Primary Doses For Immuno-Compromised Patients

If necessary please show this at your vaccine centre (ask to speak to the 'Clinical Lead')
or feel free to share with your GP Practice

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Reference Material:

JCVI

The 'Green Book'

Versus Arthritis

Crohn's & Colitis UK

Blood Cancer UK

For people with kidney disease there is coronavirus information from Kidney Care UK here

and from Kidney Charities together here
Omicron Variant Update 29.11.2021
Children and Covid Vaccine

PLEASE NOTE this document may be updated, so please do not reply on any hard copy - please use this web link https://tinyurl.com/4dnp764y for a current version - thank you. Last update 28.12.2021

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https://tinyurl.com/4dnp764y

Latest advice via Kidney Care UK

Following Boris Johnson's announcement 12.12.2021 a standard <u>'BOOSTER DOSE'</u> is now being offered to all people aged over 18, ideally by the end of December 2021. You can get this dose from 3 months after your 2nd vaccination. This 3rd vaccine is more important now due to the Omicron variant.

For individuals that were eligible for a 3rd PRIMARY DOSE, you are now eligible for a 4th BOOSTER DOSE. You can get this dose, from 3 months after your 3rd vaccination.

The idea is to boost the immune response. This is important because data shows that the vaccine effects drop after a few months and a 3rd or 4th vaccine dose gives a large boost to the immune system (this is recommended even if you have had a covid infection).

You can <u>book your boosters</u> via the 119 service, at a walk in centre, local pharmacy or via your GP Practice (if they are participating). This varies regionally.

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1. What is the difference between a THIRD PRIMARY DOSE and a booster?

This is causing a lot of confusion!

A 'THIRD PRIMARY DOSE / 3RD® DOSE' is an EXTRA dose given to SOME patients with immune problems or on medications that suppress the immune system. This is part of the initial course of vaccination. This dose is given at least 8 weeks after the 2nd dose, and is given as part of your initial course of vaccination. Although 2 doses is are usually enough for most patients, if you suffer from a dampened immune response (due to disease or some vital medication) then data suggests that you might not create an adequate protective (antibody) response to the standard 2 vaccine approach. For this reason a limited number of patients are recommended to have a THIRD PRIMARY DOSE around 8 weeks after their second dose to ensure a safe and effective response. This is separate to any booster dose. These patients will then be offered their "Booster dose" 3 months after their third primary dose.

Most people who are eligible for a **THIRD PRIMARY DOSE** will have received their second dose a while ago now, perhaps even 6 months. Please don't worry - your next dose should be counted as a 3rd dose and not a booster, and you should be called for a booster (your 4th vaccine) around 3 months after your 3rd dose. (See question 7).

There are still reports of patients not being able to record their THIRD PRIMARY DOSE on their medical records, or the NHS APP. This is being looked at, and we are reassured that the computer software will be updated. For now please get your booster on time, and it should be amended and logged correctly in due course. The main message is to get protected.

2. Why are some patients being offered a THIRD PRIMARY DOSE at 8 weeks after their 2nd dose?

Although two doses is usually enough for most patients, if you suffer from an immune problem or are on medications that suppress the immune response this might not be the case. For this reason, a limited number of patients are recommended to have a 3rd primary dose as part of their initial vaccine course to enhance their response to vaccination.

Early data from studies have shown that many patients with an immune problem or underlying health conditions, do not make an antibody response at all to vaccination or make a response that is much lower than that of someone with no underlying disorders. There will also be benefits to other parts of the immune system including T cells but these responses are still under investigation. Having no or low antibodies does not mean you don't have any protection from serious covid infection but it means you may be at higher risk than someone who has a strong antibody response.

Irrespective of age, neither you, nor your friends or family members will be able to get additional COVID-19 vaccinations just because they are required to visit other countries. This is against current UK guidelines and COVID-19 vaccination rollout rules.

3. What are the timings of the THIRD PRIMARY DOSE?

A third primary dose is given at least 8 weeks after the second dose of the vaccine. If you are on or due to start immunosuppressive treatment, speak to your specialist team about when you should get your third dose of the vaccine, as they will be able to time this around your treatment in order for the vaccine to have the best chance of working. For individuals who are on regular, long term immunosuppressive therapy, or have a constant problem with their immune system the timing of the third primary dose is likely to be less important.

4. Who should get a THIRD PRIMARY DOSE at 8 weeks after their 2nd dose?

In September 2021, the <u>JCVI announced</u> that people who have severely suppressed immune systems at the time of their first and second doses of the vaccine would be able to get a third dose. As stated above this is NOT a booster dose, but an additional 'top-up' dose to increase protection from COVID-19 for people who may not have not had a good response from the first two doses. The groups being offered a 3rd Primary Dose includes individuals with an inherited or acquired immunodeficiency at the time of their vaccination or individuals who were on immunosuppressive or immunomodulatory medication prior to or at the time of vaccination.

If in doubt, please check with your specialist team or GP.

Individuals with an immunodeficiency state include:

- Blood cancers, including patients with acute and chronic leukaemias, lymphomas, myeloma, Waldenstrom's macroglobulinaemia. For other blood cancers or if you are recovered or recovering from your blood cancer, please check with your specialist as to whether your immune system is likely to have been affected. You will be eligible for a 3rd primary dose if you have received stem cell transplant in the previous 24 months or received a stem cell transplant more than 24 months ago but had ongoing immunosuppression or graft versus host disease (GVHD)
- HIV/AIDS if current CD4 count is <200 cells/μl for adults or children
- Primary or secondary immune deficiencies

Individuals on a therapy, that affects the immune system, at the time of or around vaccination including:

- Solid organ transplant recipients on immunosuppressive therapy in the previous 6 months
- Cancer chemotherapy or radiotherapy in the last 6 months
- Prednisolone (oral steroids) 20mg or more a day for more than 10 days in the previous month or 10 mg day or more in the previous 3 months
- Methotrexate 20 mg or higher per week
- Azathioprine 3.0mg or greater per kg (of patient weight) per day
 - 6-mercaptopurine 1.5mg or greater per kg (of patient weight) per day
 - Mycophenolate 1g or greater per day in the previous 3 months.

If you are on combinations of these drugs please check with your hospital specialist.

You would be eligible for a 3rd primary dose if you received any of the following treatments in the 3 months before your 2nd vaccine:

 Anti-TNF biologics: infliximab, adalimumab, etanercept, golimumab, certolizumab pegol

- Other biologics: tocilizumab, abatacept, ustekinumab, secukinumab, belimumab
- JAK inhibitors: baricitinib, tofacitinib, upadacitinib, filgotinib
- T cell modulators: abacept, tacrolimus, cyclosporine

You would be eligible for a 3rd primary dose if you received any B cell depletion treatments in the 6 months before your 2nd vaccine:

B-cell targeted therapies including rituximab, obinituzumab, ofatumumab, ocrelizumab

If in doubt, please check with your specialist team or GP. This list is by no means comprehensive and other immune therapies will also be included – please check with your specialist.

Please see resource links at the end of this FAQ for further links.

5. Which vaccine will be used for THIRD PRIMARY DOSES (and COVID-19 boosters?)

The <u>JCVI have recommended</u> that one of the mRNA vaccines (Pfizer or a full dose of Moderna) should be used for third primary doses. This will be the case regardless of which vaccine you had before. This will mostly be the Pfizer vaccine as it is the most available mRNA vaccine at the moment in the UK.

Where neither can be offered, for example for those who have an allergy to either vaccine, the JCVI advises that the Oxford/AstraZeneca vaccine can be used for those who received this vaccine for their first and second doses. We suggest that for these unusual cases that the specialist is contacted and they may want to take advice from a specialist allergist or immunologist.

Confusingly, if a Moderna vaccine is used, it is a full dose for a THIRD PRIMARY DOSE but only half a dose for a standard booster. Please double check if you are offered a Moderna for your Third Primary Dose. For full details - see Page 23 of the Green Book HERE

6. Is it OK to mix vaccines?

Because the JCVI are recommending the mRNA vaccines for third primary doses and boosters, this means that people who previously received the AstraZeneca vaccine are now likely to receive the Pfizer or Moderna vaccine as their third dose. Studies, including the

recently published COV-BOOST study, suggest that mixing different types of vaccines in a vaccine course is safe and may in fact give a better immune response, and offer improved protection.

Although studies did not include people who were immunosuppressed, there is no reason to suggest that mixed vaccines would not be safe for immunosuppressed people.

7. If I get a THIRD PRIMARY DOSE will I also need a booster (4th dose)?

Yes. It was announced 29.11.2021 that patients who require 3 doses for their primary course will need a 'booster' or 4" dose. "Severely immunosuppressed individuals who have completed their primary course (3 doses) should be offered a booster dose with a minimum of 3 months between the third primary and booster dose. Those who have not yet received their third dose may be given the third dose now to avoid further delay. A further booster dose can be given in 3 months, in line with the clinical advice on optimal timing." LINK HERE

8. Who will contact me about my 3rd or 4th (booster) vaccine dose?

Good question!

There is currently no fixed process for this.

You might be called from a variety of places:

- You may be recalled by the same place you had your first 2 or 3 doses (primary course)
- You may be recalled by your own GP
- You may be called by your hospital specialist or the hospital that they work at
- You may receive a letter from the NHS inviting you to book

IF IN DOUBT PLEASE SPEAK TO YOUR SPECIALTY TEAM OR YOUR NURSE SPECIALIST WHO SHOULD BE ABLE TO ASSIST.

9. Where will I be able to get my THIRD PRIMARY DOSE or COVID-19 Booster?

Plans for the rollout will use the existing networks in place for the COVID-19 vaccination programme, including:

- Local vaccination services co-ordinated by GP groups (primary care networks)
- Community pharmacies
- Some limited hospital centres
- Mass vaccination centres across the country, ensuring people can access a booster dose regardless of where they live.

The NHS should contact people directly to let them know when it is their turn to get their booster vaccine and outline options available. Eligible patients are sometimes being identified from existing GP lists and sometimes by hospital specialists. If you are due please try to book via 119 or your GP or a walk in centre. Please show this FAQ if needed for background.

10. When should I hear about my 3-PRIMARY 4th BOOSTER DOSE dose?

The announcement and roll out of the boosters has been very rapid and it will be a challenge to get all eligible half a million individuals vaccinated by the target date of 11th of OctoberYou will be eligible for a 4th booster dose 3 months after your 3rd Primary Dose. We know that there has been some confusion with documenting the 3rd and 4th doses so it is important to work out when this 3 month date is for you. If you are eligible and have not yet been called please contact your specialty team or GP for advice. It will be a huge challenge to get the population vaccinated by the end of December but hopefully 4th dose boosters will be done as soon as possible.

IF IN DOUBT PLEASE SPEAK TO YOUR SPECIALTY TEAM OR YOUR NURSE SPECIALIST WHO SHOULD BE ABLE TO ASSIST.

. If you are due please try to book via 119 or your GP or a walk in centre. Please show this FAQ if needed for background.

11. What other measures should I take?

Vaccines have been very effective, but regardless of vaccine status it is still worth continuing with cautions including wearing masks, avoiding crowded areas as far as possible (particularly indoors or poorly ventilated), using a lateral flow test before social gatherings and trying to avoid close contact with others especially if they are known to be unwell. The Omicron variant is highly infectious, making these simple preventative measures even more important.

12. What should I do if I have not heard about my THIRD PRIMARY VACCINE?

If you think you are eligible for a 3rd primary vaccine and you haven't heard by 11th of Octoberyet there are a number of things you can do.

Please contact your hospital specialist to confirm that you are indeed eligible for the 3rd primary vaccine. The roll out is different in different parts of the country so it is difficult to give absolute advice about how you will be called and how to book your vaccine appointment but hopefully this will become clearer over the next few weeks. Until that time you can contact your hospital specialist, they will likely not have access to COVID-19 vaccines in clinics, but they may know how patients eligible for a 3rd dose are being delivered in their area.

Alternatively, contact your GP surgery to ask for advice and to see whether they have started contacting patients eligible for a 3^{-d} dose. A further option is to try the central covid vaccination helpline number on 119 free of charge to ask for advice.

13. What should I do if I am eligible for a THIRD PRIMARY VACCINE but have had or have already been called for a booster vaccine?

As the vaccine type and dose is the same for the 3rd primary dose or the booster vaccine in Autumn 2021 this doesn't really matter - *unless you are having a MODERNA*. A(as stated in Q5 above, if a MODERNA vaccine is used, it is a full dose for a THIRD PRIMARY DOSE but only

half a dose for a standard booster. *Please double check if you are offered a Moderna for your Third Primary Dose*. For full details - see Page 23 of the Green Book <u>HERE</u>

It is important to make sure that you don't have a 3rd primary dose and a booster this Autumn. Even though these are the same vaccine you shouldn't have these doses so close together. Once you have had your 3rd primary dose you will be eligible for a 4th dose, 3 months later.

Question: I am eligible for a 3^{-d} primary vaccine but have been called for a booster vaccine.

Answer: Great news, you have had a vaccine! You will then be eligible for a booster vaccine in 3 months time. When you are due, you should be contacted by your GP or specialist. It is not yet possible to book these online and more information about getting your 4th dose is coming.

14. Are the COVID-19 vaccines safe for me?

The currently available COVID19 vaccines are safe for people with immune problems or on immunosuppressant (including the Pfizer/BioNTech, Moderna and Oxford AstraZeneca vaccines). Studies have been done that show a 3rd dose is safe and effective at enhancing the immune response to vaccination. This is true regardless of which 2 vaccines you had first.

It is likely that you will have some pain at the site of the injection and you may have other side effects including feeling tired, achy, feverish or have a headache. If you do have side effects, they usually occur shortly after the vaccination and usually resolve within one to two days. If you have a more severe adverse reaction it is important to tell your GP or consultant so they can help you and also report it to the Yellow Card Scheme.

15. Will I know if I made a response after the THIRD PRIMARY or 4th BOOSTER DOSE?

There is currently no routine testing in the NHS to assess the response to vaccination. We also don't yet know what results from antibody testing mean in terms of whether there is a certain level which confirms protection and how long this might last. There are research studies which are exploring this in patients with immune problems. Some of these studies will send results back to patients, but importantly scientists are trying to understand what these results mean for patients eligible for the 3rd primary dose.

One study is open and recruiting now to assess antibody responses in immunosuppressed patients in the community after third primary doses – if you'd like to know more please go to the https://www.melodystudy.org website

We would discourage people from paying to have their antibody levels checked, as the results can be very difficult to interpret, and may offer false reassurance, or unnecessary concern.

16. Can I have my other vaccines eg flu or pneumonia jab at the same time as my 3. COVID-19 vaccine dose? And shingles?

Yes, the Flu and pneumonia and the COVID-19 vaccines can in theory all be given at the same time. However this is a personal decision, often for convenience and most patients would not have more than 2 vaccines at the same time. If possible please prioritise your flu and covid and postpone your pneumococcal vaccine for a week or so.

If you are having more than one vaccine they should be given in different sites (arm / leg) in case of a local reaction.

However, this will be a personal decision if you have more than one vaccine. It is important that people take up the offer of both vaccines when they receive it, so people are encouraged to get both vaccinations as soon as possible rather than waiting for the possibility of getting them together.

A UK study, called the ComFluCOV, has found that this is a safe and effective strategy. Also from a practical point of view it is often easier to arrange both Covid and Flu vaccines at the same time as a single appointment. This is especially important if a patient would struggle to return for the other vaccine at another time.

However, with the mass COVID booster vaccine campaign that has started the week beginning 13th December, aimed at increasing protection against Oomicron, it is likely that you will be offered your third primary dose or booster at a centre that might not be able to offer flu vaccine at the same time. The advice would be to prioritise having your COVID vaccine and to have your flu vaccine a week later.

**Please note that shingles vaccine should not usually be given at the same time as a Covid vaccine (7 day gap recommended), and please double check which shingles vaccine you are offered if you are immunocompromised, as the usual vaccine is live and not recommended for immunocompromised patients - who should be offered the Shingrix as an alternative.

17. What if I already had Covid-19, should I still get vaccinated?

The simple answer is YES. We are not sure that the immune response to an infection offers the same level of protection as vaccination. Advice it to wait and it should be safe to have your Covid-19 vaccination

18. How long should I wait after having a covid infection to get my vaccine?

Advice it to wait and it should be safe to have your Covid-19 vaccination as follows:

- Please wait 28 days after an infection if you are age 5-11 or age over 18.
- Please wait 12 weeks after an infection for children age 12-18

If in any doubt please discuss with your specialist team, vaccine centre or GP.

19. What about pregnancy and fertility?

All information to date suggests that the COVID-19 vaccines are not only safe in pregnancy, but also have a major and significant impact on reducing severe illness in pregnant women. All pregnant women are strongly encouraged to have the COVID-19 booster vaccination as it provides the best protection against the virus for the women and their babies. There are no medical concerns about risks to fertility and the vaccines are considered to be safe for breastfeeding. The COVID-19 vaccine can be combined with the whooping cough vaccination, or flu vaccine, both of which are routinely given in pregnancy.

Please see links below for more information on COVID-19 vaccination in breastfeeding or pregnancy:

https://www.rcog.org.uk/en/guidelines-research-services/coronavirus-covid-19-pregnancy-and-womens-health/covid-19-vaccines-and-pregnancy/covid-19-vaccines-pregnancy-and-breastfeeding/

https://www.rcog.org.uk/globalassets/documents/guidelines/2021-02-24-combined-info-sheet-and-decision-aid.pdf

20. What are the current guidelines for 5 to 11 year old children having COVID-19 vaccinations?

On 22.12.2021 JCVI guidelines were updated to recommend vaccination for high risk children aged 5-11 and also those children in this age group living in a household with someone who is immunocompromised. This is a 10mcg (1ml dose) as opposed to the 30mcg (3mls dose) in older children.

See THIS LINK

If you think your child falls in this category please book using 119 service or make yourself known at a walk in vaccine clinic (please ask to speak to the clinical lead if necessary and use a letter from your specialist team or a copy of this FAQ).

21. What are the current recommendations for children with known health conditions?

All children and young people aged 12 years or older who have reduced immune systems or receiving medicines which reduce their immune system (immunosuppression) should receive COVID-19 vaccinations, including those children on dialysis or who have had a transplant and are on immunosuppression, or those children who live with someone who is immunosuppressed.

COVID-19 vaccination is advised for all young people aged 16 years or older with Stages 3-5 Chronic Kidney Disease.

The primary vaccination schedule (**excluding booster campaign**) is different for different patient groups. Two COVID-19 vaccination doses are recommended for those patients with Stages 3-5 CKD and for those who live with someone who is immunosuppressed. Three COVID-19 vaccination doses are recommended for those patients on immunosuppression.

On 22.12.2021 JCVI announced that the Pfizer BioNTech vaccine has been approved (at a low dose) for at-risk children aged 5-11. This is a 10mcg (1ml dose) as opposed to the 30mcg (3mls dose) in older children.

We hope that the information above is correct as of 28.12.2021

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- <u>Prof Liz Lightstone</u> PhD FRCP, Professor of Renal Medicine, Imperial College London and Honorary Consultant Physician Imperial College
- <u>Prof Stephen Marks</u>, Professor of Paediatric Nephrology and Transplantation, UCL Great Ormond Street
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IF YOU NOTICE ANY INACCURACIES IN THIS DOCUMENT - OR WOULD LIKE TO MAKE ANY SUGGESTIONS PLEASE SEND ONE OF US A DIRECT MESSAGE ON TWITTER OR BY EMAIL - THANK YOU

Reference Material:

JCVI

https://www.gov.uk/government/publications/third-primary-covid-19-vaccine-dose-for-people-who-are-immunosuppressed-jcvi-advice/joint-committee-on-vaccination-and-immunisation-jcvi-advice-on-third-primary-dose-vaccination

The 'Green Book'

https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

Versus Arthritis

https://www.versusarthritis.org/covid-19-updates/vaccines-for-covid-19-your-questions-answered/

Crohn's & Colitis UK

https://www.crohnsandcolitis.org.uk/news/third-covid-19-vaccine

Blood Cancer UK

https://bloodcancer.org.uk/news/why-am-i-being-invited-for-a-third-covid-vaccine-dose/

For people with kidney disease there is coronavirus information from Kidney Care UK here

and from Kidney Charities together here

Omicron Variant Update 29.11.2021

https://www.gov.uk/government/publications/uk-vaccine-response-to-the-omicron-variant-jcvi-advice/jcvi-advice-on-the-uk-vaccine-response-to-the-omicron-variant?fbclid=lwAR0HoX-uM-lLHlAQpxm5YMrM9ngtoC-6bhqjnuMWRnwPEXKwafNyBVFeHzs

Children and Covid Vaccine

Update 22.12.2021

https://www.gov.uk/government/news/uk-regulator-approves-use-of-pfizerbiontech-vaccine-in-5-to-11-year-olds

NHS page children

https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus-vaccine-for-children-aged-12-to-15/?gclid=Cj0KCQiA5OuNBhCRARIsACgaiqW13iVClwa3DX8tDV-6Z43ZrV mgAEqGxzQ70tdQrw2TtlTDPPT0ycaAun6EALw wcB

RCPCH Page

https://www.rcpch.ac.uk/resources/covid-19-vaccination-children-young-people

Green book chapter 14a

https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a