Q&A – CLARITY Study

This Q&A is now closed. For further information and support please visit our <u>information pages</u> or contact our <u>Helpline</u> if you have questions about Crohn's or Colitis. If you need specific medical advice about your condition, your GP or IBD team will be best placed to help. We are unable to answer specific questions about the CLARITY study.

The boosters are apparently only Pfizer and Moderna, I had the Astra Zeneca, should I avoid them?

The Pfizer-BioNTech vaccine is recommended for the booster programme, even if you had a different vaccine before. A half dose of the Moderna vaccine may be offered. If Pfizer or Moderna cannot be offered, for example due to allergies, then AstraZeneca may be considered for people who received it previously. Find out more about the booster vaccination <u>here</u>.

For the third dose the Pfizer or Moderna vaccine are recommended. The Astrazeneca vaccine may be given to people who have previously had this vaccine if there is a supply issue with the Pfizer or Moderna vaccine. If you are eligible for a third dose, you may therefore be offered a different vaccine to your first two vaccine doses. In particular, people who previously received the AstraZeneca vaccine are now likely to receive the Pfizer or Moderna vaccine as their third dose. Find out more about the third dose vaccination <u>here</u>.

How does Ustekinumab compare to other biologics?

Ustekinumab is an anti-interleukin biologic drug and was not specifically studied in the CLARITY study. It is not an anti-TNF drug and works differently to both infliximab and vedolizumab. Please see the response to question **2** for more information about ustekinumab.

We also have further information on comparison of <u>biologic drugs</u>. Ustekinumab is one of the immunosuppressant drugs that the <u>VIP study</u> plans to explore.

I'm on Ustekinumab - is that akin to infliximab in causing increased risk of respiratory infection or akin to vedolizumab which is not associated with causing this?

Response from Tariq Ahmad: "Ustekinumab does not increase the risk of respiratory infection or impair pneumococcal or tetanus vaccine response in patients with psoriasis nor influenza vaccination response in IBD patients. Further data relating to the impact of ustekinumab on COVID-19 vaccine responses will be available in the next 6 weeks."

To learn more about these drugs, please refer to our information sheet <u>here</u>.

Regarding the CLARITY presentation, the map seemed to show no participants in Northern Ireland - what was the reason for this?

Response from Tariq Ahmad "Northern Ireland sites were invited to participate but did not have capacity to support the project. This has been a problem with our previous multi-site projects."

Is there a plan for the finger prick blood tests for routine medication tests be rolled out to other hospital trusts?

Response from Tariq Ahmad "We hope to make home finger prick testing for routine therapeutic drug monitoring available to people with IBD across the UK. However, currently this service is not funded outside of Exeter."

How do patients requiring a third dose of the Covid-19 vaccine because of taking Adalimubab or a similar biologic (not a booster) get our GPs to administer them? I am reluctant to clog up the IBD Nurses Helpline. Is there some way the Consultants could let the GPs know directly which of their patients require this third dose?

If eligible, you should be contacted with information on how to book your third vaccine dose. To read more about the third dose, whether you are eligible and how you will be invited you can read <u>our</u> <u>news article</u>. We have also created a <u>letter</u> that you can show your GP or hospital team to make them aware of your situation.

Do you have any information for people taking Adalimumab (Amgevita)?

Adalimumab was not specifically studied in the CLARITY study, but it is also an anti-TNF drug (like infliximab). Researchers of CLARITY have predicted that similar results would be seen with other anti-TNFs.

People who were taking adalimumab around the time of their first and second vaccination are eligible for a <u>third vaccine dose</u>.

What about other anti-TNF drugs? Which drug is Adalimumab closest to in the CLARITY study, infliximab or vedolizumab? What about ustekinumab or other biologics?

Response from Tariq Ahmad: "We are reasonably confident that [the results from CLARITY] applies to all anti-TNF drugs. We have done some work with adalimumab showing pretty similar results"

Adalimumab is an anti-TNF drug and is the same class of drug as infliximab while vedolizumab is classified as an anti-integrin and works very differently in the body.

See the response to question 2 for further information about ustekinumab.

For more general information on biologic medicines please see our information sheet.

If infliximab patients have a lower antibody response to the vaccine, are these patients likely to be offered a booster jab, and does this translate to other immunosuppressant biologics?

The Joint Committee on Vaccination and Immunisation (JCVI) has recommended that any patients taking Infliximab in the three months before their first or second COVID-19 vaccine dose, should be offered a third dose of vaccine. See <u>What is the third COVID-19 vaccine dose?</u> for more information. It is likely that people who have had the third dose will also be eligible for a booster dose, but we are waiting on further advice from the JCVI regarding this.

I've had a major flare of my UC during the summer, for about two and a half months. I didn't leave the house for 8 weeks, eventually the flare was brought under control by Prednisolone. I'm currently on 20mg, will go down to zero over the next three weeks. I have returned to work physically this week, after working from home for over 18 months and not traveling anywhere. Now I'm travelling on busy London trains. I would like to receive my 3rd jab ASAP. I had Astra Zeneca 1st shot in Feb 2021 and the 2nd in May 2021. So I assume I should wait to get off Prednisolone before getting the jab. Also, what is the best vaccine to take as a 3rd dose for please? I was hoping to get Moderna as I understand it produces the strongest level of antibodies. But I understand people are getting half a dose of Moderna as a booster. Presumably higher risk patients in my position could get a full dose of Moderna as a 3rd jab. So, in short, when should I get the 3rd jab and what's the best one - Pfizer or Moderna - and what dosage.

If you are eligible for a third dose, you may be offered a different vaccine to your first two vaccine doses. In particular, people who previously received the AstraZeneca vaccine are now likely to receive the Pfizer or Moderna vaccine as their third dose, as recommended by the JCVI.

Your IBD Team may recommend that you finish your course of steroids before you have the COVID-19 vaccine. This is because the vaccine will be more effective if you are not taking a higher dose of steroids. However, it is still safe to take the vaccine while on steroids. See <u>What is the third COVID-19</u> <u>vaccine dose?</u> for more information

What resources are available to those who wish to engage and participate with those in their local network? I currently do not have anyone I can talk to about IBD apart from my nurse and would like to build a network with those going through similar experiences."

Crohn's & Colitis UK coordinate 50 local networks across the UK. These bring local people affected by Crohn's and Colitis together and raise awareness of the conditions with members of the public. From educational talks to social events, local networks give people the comfort and confidence to live freer and fuller lives. You can find out more about our <u>local networks</u> as well as other <u>wellbeing support</u> for people affected by Crohn's and Colitis.

We also offer people affected by Crohn's or Colitis the chance to join a virtual social event with others across the UK. These events are be a chance to chat, share experiences and potentially learn from others. Find out more about our <u>virtual social events</u>.

How were people/sufferers asked to do the tests??!! I never had any info that I'm aware of??!!

From the information given we are unable to answer this question. It is not clear which tests this is referring to.

Are the figures for the general public getting Covid or being hospitalised after 2 vaccines much different for the figures for the people in this study?

The researchers of the CLARITY study are currently in the process of comparing their data with data from the general public (from another study). This will help to see whether there is a difference in breakthrough infections post vaccination between the general public and people with Crohn's and Colitis who were immunosuppressed at the time of their vaccine doses.

"Adult household contacts should get a third dose". Will GPs or national vaccination service be aware of and operating to this guideline?

The JCVI has issued guidance to all GPs and vaccination sites which states that adult household contacts of immunosuppressed individuals should be offered a booster dose of COVID-19 vaccine. For further information see <u>booster vaccine dose</u>.

When should the 3rd dose of the vaccine be taken with someone on a 2-week cycle with adalimumab?

The British Society of Gastroenterology (BSG) recommends that, if possible, you should have your vaccine when your immune system is at its strongest. If you are currently going through a treatment cycle or about to start or change immunosuppressant treatment, your IBD team should be able to advise you about the best timing for your vaccine dose. This is recommended because the vaccine may be less effective once you are more immunosuppressed. See <u>What is the third COVID-19</u> <u>vaccine dose?</u>

Should we work from home if taking biologics?

Speak to your employer if you are concerned about your situation at work. You might wish to work out your individual <u>risk</u> of developing serious illness from COVID-19 and how this may impact your safety at work. Remember that your risk level may change if you are in a flare, come out of a flare or change medications. If your condition changes make sure to reassess your risk level and let your employer know. See our <u>Work and finance information</u> if you are concerned about your situation at work.

I am now on Infliximab subcutaneous injections every two weeks as I am housebound because of several vertebral fractures due to osteoporosis. What timeframe should I get my third vaccination done - halfway in between the doses?

The British Society of Gastroenterology (BSG) recommends that, if possible, you should have your vaccine when your immune system is at its strongest. If you are currently going through a treatment cycle or about to start or change immunosuppressant treatment, your IBD team should be able to advise you about the best timing for your vaccine dose. This is recommended because the vaccine may be less effective once you are more immunosuppressed. See <u>What is the third COVID-19</u> <u>vaccine dose?</u> for more information.

If not on infliximab 8-weekly but on 2-weekly injections, what is nadir for 3rd dose?

The British Society of Gastroenterology (BSG) recommends that, if possible, you should have your vaccine when your immune system is at its strongest. If you are currently going through a treatment cycle or about to start or change immunosuppressant treatment, your IBD team should be able to advise you about the best timing for your vaccine dose. This is recommended because the vaccine may be less effective once you are more immunosuppressed. See <u>What is the third COVID-19</u> <u>vaccine dose?</u> for more information.

I am on Methotrexate 8 weekly cycle - how does that fit with weekly injections?

The British Society of Gastroenterology (BSG) recommends that, if possible, you should have your vaccine when your immune system is at its strongest. If you are currently going through a treatment cycle or about to start or change immunosuppressant treatment, your IBD team should be able to advise you about the best timing for your vaccine dose. This is recommended because the vaccine may be less effective once you are more immunosuppressed. See <u>What is the third COVID-19</u> <u>vaccine dose?</u> for more information.

Were the participants shielding and therefore unlikely to get the infection in the CLARITY study?

Response from Tariq Ahmad: "The questionnaire that was sent out did capture information about shielding behaviour...so we tried to control for that in the comparison of infliximab versus vedolizumab. But it does make it difficult to compare [CLARITY results] with any other data"

I had a Pfizer vaccine in April, and I've been suffering since! I had a very bad flare up and I'm currently in hospital under treatment. Should I go for my 3rd vaccine? I'm taking IV steroid at the moment, and it seems my body responding well.

Response from Tariq Ahmad: "We have looked at this.... vaccination does not appear to impact disease activity and as far as we can see disease activity does not seem to impact vaccine response. If you are given a course of steroids to treat your flare or you are started on a new drug, that may impact the response to vaccination."

For more on vaccination and flares see our vaccine page.

I am 47 and I want to know if I am allowed to have the jab for my IBD, I am also a carer to my vulnerable husband.

Use these links to find out whether you are eligible for the <u>booster vaccine dose</u> or the <u>third vaccine</u> <u>dose</u>.

Is there a greater reduction in antibody response if you are taking adalimumab fortnightly and azathioprine daily?

Response from Tariq Ahmad: "Lower antibody levels are observed in participants who take both an immunomodulator [such as azathioprine] and infliximab when compared to infliximab alone. This is seen following one and two doses of vaccine. We have not specifically investigated antibody levels after vaccination in people treated with adalimumab but expect to see similar results."

Is this advice to be taken with caution given the data from CLARITY is based on the original virus and not taking into account new variants alongside change in lifestyle i.e previously shielding patients?

Response from Tariq Ahmad: "Many patients with IBD treated with biologics and immunomodulator drugs were shielding or following enhanced social distancing prior to 1st April 2021. Therefore, it is

possible that we may have underestimated the impact of biologics and immunomodulator drugs of acquiring SARS-CoV-2. However, based on the data from CLARITY I am confident that the risk of serious disease and hospitalisation following 2 doses of vaccine is very low. Only 1% of patients with PCR confirmed infection after 2 doses of vaccine were hospitalised. Reassuringly, most of the PCR confirmed infections which have occurred since vaccination have occurred since the delta variant was dominant in the UK."

Is it safe to have the flu vaccination at the same time or close to the 3rd dose of the COVID vaccine?

The COVID booster vaccine and annual flu vaccination can be given at the same appointment. In some cases, they may be given separately for practical reasons. It is important to get your <u>flu jab</u> if you are offered one.

I'm a single parent with Crohn's on an 8 weekly Infliximab hospital infusion with a child who goes to secondary school. I've had my 2nd Astra Zeneca vaccine. Would you advise I shield away from my child until 3rd dose or take the risk? Also having had the AZ vaccines, can I have the Pfizer or Moderna, will they be as affective?

Data from the CLARITY study suggest that hospitalisations due to COVID-19 are very low after the first two doses of vaccine. Individuals will need to make decisions based on their own personal circumstances about what activities they do or don't feel comfortable doing.

If you are eligible for a <u>third dose</u>, you may be offered a different vaccine to your first two vaccine doses. In particular, people who previously received the AstraZeneca vaccine are now likely to receive the Pfizer or Moderna vaccine as their third dose, as recommended by the JCVI.