Update on COVID- 19, vaccination and access to therapies

Dear Immunodeficiency UK supporter,

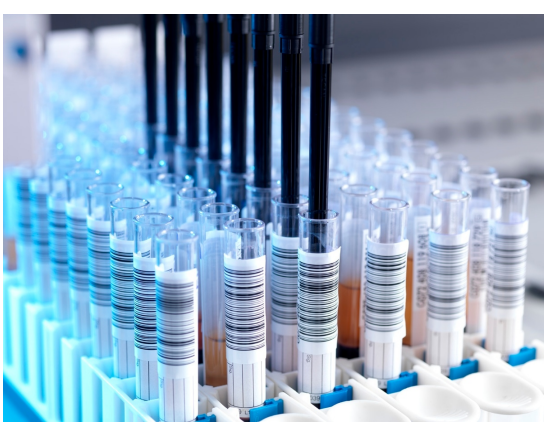
Welcome to this special edition newsletter to bring you up to date on recent developments concerning COVID including our advocacy activities and an update from Parliament.

Emergence of COVID-19 neutralising antibodies in donated US plasma

Data from a recent study indicates rising levels of COVID-19 neutralising antibodies in plasma donations in the USA. The study, conducted by Takeda, examined 176 lots of collected plasma over the period March 2020 to January 2021.

No COVID-19 antibodies were found over the period March to August 2020 but by September, that year, 12 of 26 lots were found to have antibodies, consistent with the rising incidence of COVID infection the US population. Using data extrapolation, the study suggests that high levels of COVID-19 neutralising antibodies will be present in plasma pools from July 2021. Factoring in the time for fractionation, safety testing and batch release, this could result in the availability of IG products high in anti-COVID antibodies in early 2022.

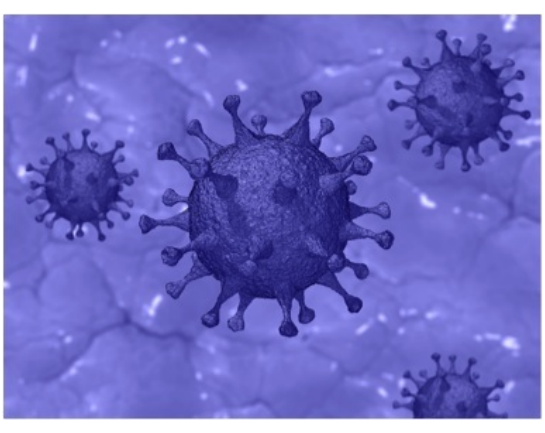
C-Velvet study



NHS Blood and Transplant (NHSBT) is carrying out a study, called C-Velvet, in the Birmingham region aimed at confirming whether vaccination creates a huge increase in antibody levels in people who have already had coronavirus.

Dr Lise Estcourt, Head of NHSBT's Clinical Trials Unit, who is the study lead, said: "Previous small studies show people who've already had coronavirus generate a significantly higher antibody response to the vaccine – around 100 times higher or more. They also found an increase in the cross reactivity of the antibodies against different viral strains. Our C-Velvet study could have two benefits for potential treatments. We may identify plasma 'super donors' who provide the very high antibody levels needed for any trial of hyperimmune plasma. Secondly, our study could inform the development of monoclonal antibody therapies which react against more viral variants."

Access to anti-COVID monoclonal antibody treatments for the immunocompromised



Trials using the monoclonal antibody therapy treatment, Regeneron, have shown it significantly reduced the risk of death; length of hospital stay and the likelihood of needing a ventilator to breathe.

The results of the PROVENT clinical trials, which researched a combination of two investigational monoclonal antibodies for the prevention of Covid-19, are expected soon.

According to this article countries, such as France and Germany, have already issued guidance to health providers as to whom who should be offered these types of treatments, whilst the UK is lagging behind in making these type of therapies available to patients.

In May Immunodeficiency UK wrote to the Medicines & Healthcare products Regulatory Agency (MHRA) asking for an update on access. In the response the MHRA say that 'We fully appreciate the concern these patients have about the limitations of vaccines and they are at the forefront of our efforts to find the most appropriate treatments for them working with our healthcare partners including the public health bodies' and are 'committed to providing safe and timely access to treatments for UK patients; we give priority to products intended to treat COVID-19 disease.'

Immunodeficiency UK also wrote to the Department of Health and Social Care highlighting the need for a 'COVID lockdown exit strategy' for the immunodeficiency community so that they can achieve parity with people who are able to benefit from the COVID vaccination programme. Their full response can be found here.

We welcomed the news in the last paragraph - 'you may wish to know that treatments containing COVID-19-neutralising antibodies have been secured from AstraZeneca for those who will not be able to benefit from a COVID-19 vaccine.'

Immunodeficiency UK will continue to keep you informed of all developments.

Question from Immunodeficiency UK to Lord Bethell, (Parliamentary Under Secretary of State at the Department of Health and Social Care):

At a recent Specialised Healthcare Alliance meeting Susan, our CEO was able to ask Lord Bethell the following question 'The immunodeficiency community feels abandoned and frightened as the UK move towards full easing of COVID restrictions. This community, who, by the nature of their underlying condition, are unable to benefit directly from the COVID vaccination programme. What is the revised COVID risk assessment and associated strategy for people who have immunodeficiency and what plans are there for access to synthetic monoclonal antibody treatments that would offer them some protection against COVID?'

Answer received:

- The Government is aware of the concerns from the immunodeficiency community regarding the impact of COVID-19, and lack of relative protection offered by vaccines for certain groups. The issue is a key focus for Ministers, and they remain optimistic about progress within this area
- It is important to note that vaccines are safe for immunodeficiency patients, however, vaccines may not be as effective in generating an immune response
- The Minister leads the new Antivirals Taskforce which aims to identify a suitable treatment to compliment the vaccine and therapeutic programmes for immunodeficiency patients
- UK Research and Innovation is providing funding for a study which will examine the response to COVID-19 vaccines in clinically at-risk groups, including those with an immunodeficiency and some cancers.

Strategy promised for the immunocompromised

On the 14th June Susan, our CEO and Gemma Peters, CEO of Blood Cancer UK, took part in a zoom meeting with Professor Jonathan Van-Tam, the Deputy

Chief Medical Officer (DCMO) and other NHS officials. The invitation was extended following lobbying by both charities. During the meeting Professor Van-Tam assured us that the government is working on a comprehensive strategy plan for the immunocompromised groups who have little or no vaccination response. He was unable to give a firm deadline on when the plan would be published as its content is dependent on the results from different COVID research trials, but it should be available in Autumn. Immuno-deficiency UK will keep you informed of developments.

COV-Boost - vaccine booster program

University Hospital Southampton NHS Foundation Trust's COV-Boost vaccine trial is studying the use of seven different COVID-19 vaccines when given as a third dose.

This study is being led by University Hospital Southampton NHS Foundation Trust (Chief Investigator Professor Saul Faust), and delivered by a network of trial sites across the UK. The study is funded by the Vaccine Task Force and the National Institute for Health Research (NIHR). The trials will include people with primary and secondary immunodeficiency. Final decisions on what a booster programme would look like will depend on the data from ongoing clinical trials and advice from the independent medical experts at the Joint Committee on Vaccination and Immunisation (JCVI).

Vaccination of children against COVID-19

An abstract from the Strategic comms team at the DHSC, dated 25-06-2021 says *"Ministers have not received advice and no decisions have been made on whether people aged 12 to 17 should be routinely offered COVID-19 vaccines."* A Department of Health and Social Care spokesperson said: *"The government will continue to be guided by the advice of the JCVI and has asked for its formal recommendation."*

It is our understanding that children in some clinically extremely vulnerable subgroups may be offered a COVID vaccine, but recommendations have yet to be made.

Written questions in Parliament concerning the immunocompromised community

22nd June 2021

Q. Baroness Altmann: To ask Her Majesty's Government what plans they have to protect individuals who are immuno-compromised and therefore cannot be vaccinated against COVID-19; and whether they plan to offer those individuals plasma from people who have either (1) recovered from COVID-19, or (2) been fully vaccinated.

A. Lord Bethell (Parliamentary Under Secretary of State at the Department of Health and Social Care): All immunocompromised people have been offered a COVID-19 vaccination. We continue to monitor vaccine efficacy to identify groups, such as the immunocompromised, who may require additional support. Immunocompromised individuals are a priority cohort for research into therapeutic and prophylaxis treatments such as monoclonal antibody therapies, novel antivirals and repurposed compounds.

It is not yet possible to determine the exact cohort of patients who may benefit from these treatments, as this will depend on results released by ongoing trials as they conclude, licensing approval from the Medicines and Healthcare products Regulatory Agency and deployment planning. We are taking steps to ensure supply of treatments in the event that they are found to be effective. We are developing options for further clinical trials where necessary.Convalescent plasma from people who have recovered from COVID-19 was found to not provide a clinical benefit in hospitalised patients in the RECOVERY clinical trial. However, we keep the evidence under review for all neutralising antibody therapies including convalescent plasma. The NHS Blood and Transplant study C-VELVET will provide information on the levels of antibodies produced by patients post vaccination and could support further research and development of antibody therapies.

21st June 2021

Q. Yasmin Qureshi MP: To ask the Secretary of State for Health and Social Care, what assessment he has made of the potential merits of testing people with a suppressed or no immune system for antibodies after they have been vaccinated against covid-19.

A. Nadim Zahawi (Parliamentary Under-Secretary for the DHSC): Virus Watch data, supported by NHS Test and Trace, provides information regarding patients' antibodies and this includes immunocompromised patients as part of their cohort. The data suggests some protection against COVID-19 but is only one measure and does not look at cellular immunity which may be more important in terms of long-term immunity.

Each antibody test will vary in its sensitivity and specificity and there is currently no agreed level of antibody which indicates someone is immune. The Joint Committee on Vaccination and Immunisation will continue to review evidence on the use of vaccines in those with immunosuppression and will update its advice as necessary.

Q. Damian Hinds MP: To ask the Secretary of State for Health and Social Care, pursuant to the Answer of 27 May 2021 to Question 4578 on exploring prioritisation of immunocompromised individuals for the planned autumn booster covid-19 vaccine programme, what key clinical studies will be considered in the decision-making process for that programme; and when the data used to inform decisions will be published.

A. Nadim Zahawi (Parliamentary Under-Secretary for the DHSC): The Department has asked the Joint Committee on Vaccination and Immunisation (JCVI) to consider the need for and timing of additional doses of COVID-19 vaccines. The JCVI will consider available evidence from a range of sources in its deliberations but is not able to confirm which studies will be available at this stage. The JCVI's deliberations will be published in due course.

Q. Lord Mendelsohn: To ask Her Majesty's Government what assessment they have made of the antibody response in immunocompromised individuals following trials of a third dose of the COVID-19 vaccine.

A. Nadim Zahawi (Parliamentary Under-Secretary for the DHSC): The COV-BOOST study was commissioned by the Department through the National Institute for Health Research and funded by the Vaccine Taskforce, as part of the National Immunisation Schedule Evaluation Consortium. This study launched on 19 May and initial findings are expected in September. The study will provide vital data on the impact of a third dose on patients' immune responses and will help inform decisions by the Joint Committee on Vaccination and Immunisation on potential plans for a booster programme from autumn this year.

Q. Lord Mendelsohn: To ask Her Majesty's Government what plans they have, if any, to reintroduce shielding for clinically extremely vulnerable individuals who (1) are immunocompromised, or (2) have not been protected by two doses of the vaccine, but who are expected to return to work and normal life when the COVID-19 pandemic restrictions are lifted.

A. Lord Bethell (Parliamentary Under Secretary of State at the Department of Health and Social Care): Shielding is only introduced where absolutely necessary as the measures are restrictive and can have a negative impact on individuals mental and physical wellbeing. Prevalence levels of COVID-19 and the risk faced by those considered as clinically extremely vulnerable are currently low and as a result the reintroduction of shielding is not required. However, the Government continues to monitor the situation and would not hesitate to reintroduce shielding measures, either locally or nationally, if necessary. Work is ongoing to better understand the effectiveness of COVID-19 vaccines in the clinically extremely vulnerable population, particularly those who are immunocompromised or immunosuppressed. The results of this work, along with the epidemiological situation at the time, will inform whether any further guidance or support is required for certain groups of clinically extremely vulnerable people.

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