IMMUNO DEFICIENCY UK | Supporting families affected by primary and secondary immunodeficiency

Questions asked in the House of Lords by Lord Mendelsohn on behalf of Immunodeficiency UK

Dated 6th January 2022

Response to Covid vaccinations

Q. To ask Her Majesty's Government what plans they have, if any, to test people with immunodeficiencies for their individual responses to COVID-19 vaccinations.

Lord Kamall 1 Dec 2021
The UK Health Security Agency is working with a range of partners, such as the University College of London, to monitor the effectiveness of COVID-19 vaccinations in clinical risk groups, including those with immunosuppression. The VirusWatch study is underway to monitor antibody response following vaccination among individuals with immunosuppression.

As part of the COVID-19 Immunity National Core Study, the UK Research and Innovation OCTAVE study is examining the effectiveness of vaccines in clinically at-risk groups. This includes vaccine responses in patients with certain immunosuppressed conditions.

Q. To ask Her Majesty's Government what plans they have to monitor (1) immunocompromised patients' antibody levels, and (2) their variation over time, in response to the rollout of the third primary dose vaccination.

Lord Kamall 16 Dec 2021
The UK Health Security Agency (UKHSA) is monitoring the effectiveness of COVID-19 vaccinations in clinical risk groups, including those with immunosuppression. The VirusWatch study monitors antibody response over time following COVID-19 vaccination, including the third primary dose, among individuals with immunosuppression.
As part of the COVID-19 Immunity National Core Study, the UK Research and Innovation OCTAVE study is examining the immune response to COVID-19 vaccines in clinically at-risk groups. This includes vaccine responses in patients with certain immunosuppressed conditions. These analyses will monitor the duration of immunity from COVID-19 vaccination.

Access to anti-COVID therapies

Q. To ask Her Majesty's Government what plans they have to rollout Ronapreve as a prophylactic preventative treatment for COVID-19?

Lord Kamall 1 Dec 2021
On 20 August 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) approved Ronapreve (casirivimab and imdevimab) as the first monoclonal antibody combination product indicated for use in the prevention and treatment of acute COVID-19 infection.

The current supply of Ronapreve is limited globally, therefore the clinical policy prioritises the most vulnerable hospitalised patients for whom this treatment will provide the most benefit, which is supported by the clinical evidence. There are no current plans to make Ronapreve available for prophylaxis. We also anticipate that further neutralising monoclonal antibody treatments will be submitted for evaluation for a marketing authorisation by the

MHRA in the next few months. If approved, these could become available for community treatment or prevention use.

Note from Immunodeficiency UK: *Ronapreve has since been found to be less effective against the Omicron variant and the monoclonal antibody treatment Sotrovimab is now being used.*

Q. To ask Her Majesty's Government what plans they have to evaluate AZD7442 for emergency use as a preventative treatment against COVID-19; and what are the timelines for its approval.

Lord Kamall 1 Dec 2021
We continue to monitor the emerging data for AstraZeneca's long-acting antibody therapy, AZD7442. AstraZeneca are discussing potential approval for the therapy with the Medicines and Healthcare products Regulatory Agency. We anticipate that further neutralising monoclonal antibody treatments will be submitted for evaluation for a marketing authorisation by the MHRA in the next few months. These treatments could become available for community treatment or preventative use.

Q. To ask Her Majesty's Government what plans they have to secure stocks of AstraZeneca's treatment AZD7442 as a prophylactic preventative therapy against COVID-19 infection.

Lord Kamall 1 Dec 2021
We are unable to provide the information requested as it is commercially sensitive. The Department published a Prior information Notice in Find a Tender Service on 5 October 2021 inviting suppliers to submit an Expression of Interest on neutralising antibody treatments they are developing for treating and preventing COVID-19. The engagement enables the Department to monitor development of all neutralising monoclonal antibodies for treatment and prevention of COVID-19.

Immunoglobulin management and supply

Q. To ask Her Majesty's Government why they have not yet appointed a supplier of immunoglobulin products; and when they expect to have completed the tender process.

Lord Kamall 16 Dec 2021
The Department, NHS Blood and Transplant and NHS England and NHS Improvement are working to create a long-term domestic supply of plasma in England which can be used to manufacture immunoglobulins. The tender notice is due to be issued early 2022, with the aim of appointing a fractionator during that year.
The production of medicines is complex and highly regulated and materials and processes must meet rigorous safety and quality standards. Subject to the necessary regulatory approvals, we expect United Kingdom plasma sourced immunoglobulins to be available to National Health Service patients in 2024.

Q. To ask Her Majesty's Government when they expect patients to receive treatment with products made from UK plasma.

> *Note: until 2016 the UK had a plasma fractionator – BPL Ltd, but the government sold off its 20% NHS stake – see [Create Group Corporation agrees to acquire Bio Products Laboratory Ltd. | Bain Capital]*

Lord Kamall 16 Dec 2021
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The production of medicines is complex and highly regulated and materials and processes must meet rigorous safety and quality standards. Subject to the necessary regulatory approvals, we expect United Kingdom plasma sourced immunoglobulins to be available to National Health Service patients in 2024.

Q. To ask Her Majesty's Government why patients dependent on immunoglobulin are experiencing (1) treatment "holidays", (2) longer waits between treatments, and (3) smaller doses; and what steps they are taking to secure (a) a stable, and (b) a secure, supply of immunoglobulin.

Lord Kamall 10 Dec 2021
Clinicians are responsible for the management of patients, including dosage and dosing intervals, with the oversight and governance of sub-regional immunoglobulin assessment panels. The decision to recommend treatment holidays, extended intervals between treatment and reduction of doses in selected patients is based on consensus recommendations from United Kingdom and European experts and draft European Summary of Product Characteristics for immunoglobulin.
The immunoglobulin management plan, currently being produced, will enable the management of immunoglobulin in times of significant supply issues and ensure equal access of immunoglobulin to all patients. The Department has well established processes to deal with medicine shortages and works closely with the Medicines and Healthcare products Regulatory Agency, the pharmaceutical industry, NHS England and NHS Improvement and others operating in the supply chain to prevent shortages and ensure that risks to patients are minimised when shortages do arise.

Q. To ask Her Majesty's Government how many patients in the last year have (1) been taken off therapy, (2) had to change immunoglobulin product, (3) been advised of treatment holidays, or (4) received reduced doses, because of a shortage of immunoglobulin.

Lord Kamall 13 Dec 2021
The information requested is not held centrally, as such decisions are made by expert clinicians locally.

Q. To ask Her Majesty's Government how the NHS is monitoring (1) the health of patients who (a) have been denied access to immunoglobulin therapy or (b) are on sub-optimal care in relation to immunoglobulin therapy, and (2) the additional cost of patients (a) not having immunoglobulin treatment or (b) being on sub-optimal treatment.

Lord Kamall 13 Dec 2021
Clinicians are responsible for the ongoing monitoring and assessment of patients who receive sub-optimal immunoglobulin therapy and those who have not received immunoglobulin therapy through existing mechanisms to review patients, such as annual reviews and outpatient face-to-face or virtual appointments.
Sub-regional immunoglobulin assessment panels provide oversight and scrutiny for all patients receiving immunoglobulin therapy. For all disorders where immunoglobulin is used as treatment, treatment decisions are based on NHS England and NHS Improvement's clinical commissioning criteria for the use of therapeutic immunoglobulin. For patients with secondary antibody deficiency, consensus recommendations from experts in the United Kingdom and Europe and draft European Summary of Product Characteristics for immunoglobulin provide additional evidence to support temporary suspension, reduction in dose or withdrawal of immunoglobulin in selected patients. NHS England and NHS Improvement are unable to quantify the additional cost of patients not receiving immunoglobulin treatment and who may be receiving an alternative treatment such as rituximab or plasma exchange.

Q. To ask Her Majesty's Government how many newly-diagnosed patients with (1) primary or (2) secondary immunodeficiency in the UK, who fit the eligibility criteria for immunoglobulin use, have been refused access to immunoglobulin this year.

Lord Kamall 13 Dec 2021
The information requested is not held centrally. However, the clinical assessment of individual patients will determine the most appropriate pathway to meet their needs.

Q. To ask Her Majesty's Government what contingency planning the NHS made to ensure continuity of supply for immunoglobin for patients at the start of the COVID-19 pandemic.

Lord Kamall 13 Dec 2021
At the start of the COVID-19 pandemic, NHS England and NHS Improvement's national commissioning criteria for the use of therapeutic immunoglobulin provided expert guidance for the management of patients on immunoglobulin treatment. There is a demand management plan available for use as a contingency to address any instance of constrained supply.
At present, supplies of immunoglobulin are available for patients who require it. An updated demand management plan is currently being developed with updated commissioning criteria to ensure immunoglobulin remains accessible.

Q. To ask Her Majesty's Government what assessment they have made of whether supplies of immunoglobin are sufficient to meet current demand; and what steps they are taking to ensure that all patients can be maintained on the therapy they need.

Lord Kamall 13 Dec 2021
At the start of the COVID-19 pandemic, NHS England and NHS Improvement's national commissioning criteria for the use of therapeutic immunoglobulin provided expert guidance for the management of patients on immunoglobulin treatment. There is a demand management plan available for use as a contingency to address any instance of constrained supply.
At present, supplies of immunoglobulin are available for patients who require it. An updated demand management plan is currently being developed with updated commissioning criteria to ensure immunoglobulin remains accessible.

Q. To ask Her Majesty's Government how the NHS in England is monitoring the health outcomes of patients who no longer fit the new eligibility criteria for immunoglobulin use.

Lord Kamall: 17th Dec 2021
Clinicians are responsible for the ongoing monitoring and assessment of the health of their patients, using processes such as annual reviews and outpatient face-to-face or virtual appointments. Sub-regional immunoglobulin assessment panels provide oversight and scrutiny for all patients receiving immunoglobulin therapy.

Q. To ask Her Majesty's Government how many challenges have been made to the sub-regional immunoglobulin assessment panels in the last year concerning access to immunoglobulin therapy; and how many decisions have been overturned.

Lord Kamall 16 Dec 2021
The information requested is not held centrally. Clinical decision-making information is held by the relevant provider organisation hosting the panels.

Q. To ask Her Majesty's Government what communications have been issued by the NHS in England about the immunoglobulin shortage to patient groups supporting people with immunodeficiency; and whether the NHS in England has communicated directly with patients to explain the situation and how it will affect them.

Lord Kamall: 20 Dec 2021

With the input of clinicians, professional bodies and patient groups*, NHS England and NHS Improvement and the UK Primary Immunodeficiency Network have developed a patient information leaflet which was issued to National Health Service trusts on 8 November 2021, with a request to discuss and share with patients as part of individual clinical conversations. NHS England and NHS Improvement have also shared the leaflet with patient groups to circulate to affected members.

The patient information leaflet highlights that, due to the COVID-19 pandemic, fewer people have been able to donate blood, which has impacted the availability of immunoglobulin products both globally and in the United Kingdom. The patient information leaflet also explains what the impact of the global shortage of immunoglobulin products may mean for UK patients and how they can access support. A copy of the patient leaflet, *Immunoglobulin replacement therapy: Information for patients from the NHS and the UK Primary Immunodeficiency Network* is attached.

**Please note that Immunodeficiency UK had pressed the NHS for information for patients from March 2021 when the immunoglobulin shortage started to impact patients. We were sent the final leaflet on the 18th November 2021.*

Ends