Questions from the public: September 2022 Board meeting

# Sam mentions restrictions on expenditure to secure adequate staffing. However, I did hear someone mention that you are under budget by circa £1m and are looking to save it for DHSC. Can you please expand on this and clarify if it is restriction on expenditure that is really pushing the capacity/capability.

In line with expectations from the Department of Health and Social Care (DHSC), we have taken a very rigorous approach to recruitment and only recruited to vacancies that are critical to requirements. This has contributed to a forecast £1m underspend and this has been offered back to DHSC to help with wider funding challenges across the department.

# Are there plans for the next modular updates? E.g., review of impact of severity modifier and issues re removal of end of life criteria.

A map of future potential modular updates is being prepared. However the focus for 2022/23 is implementing the methods and process manual agreed in January 2022 and the proportionate approach to technology appraisal business plan priority.

# Reviewing the board papers which talks about updating the manual for NICE digital guidelines - it appears that the first element of this update will be open to public consultation in October. When might this be expected in October? Is there any clarity on timing? Thank you.

The consultation opened on 20 October and closed on 1 December. A further two planned modules of updates are planned in 2023.

# Sam has mentioned the importance of horizon scanning and learning from data. As Sotorovimab no longer appears to be effective against current Omicron variants, why isn’t NICE moving up focus on Bebtelovimab? Many of us CEV cannot take paxlovid or remdesivir.

NICE’s technology appraisal programme is only able to review products that have received, or are due to receive marketing authorisation. Bebtelovimab has not been identified as seeking marketing authorisation and therefore has not been referred to NICE.

# Where can more information be found on the innovative pathway for devices and what stage is it in (i.e. still pilot stage or being rolled out permanently?)

The innovative devices access pathway is currently in the early design phase. Further information is available on [NICE’s website](https://www.nice.org.uk/about/what-we-do/digital-health/office-for-digital-health#innovative-devices-access-pathway).

# Great to see in the papers the next stage for COVID-19 MTA, are there any further updates on the assessment of COVID-19 therapeutics?

# The first committee discussion is due to take place in October and the next meeting is scheduled for January.

# The following questions were received on Evusheld. Given the volume of questions received, it was agreed at the meeting that it would not be possible to provide an individual response to each and instead a statement was given.

# Please explain why studies and significant large-scale tests, evidence and data already available that strongly recommends use of Evusheld to protect the immunocompromised are being ignored?

# 34 countries and all of G7 are using Evusheld. So please explain why the call of 20 UK charities and 125 UK clinicians, all of whom are backing Evusheld being made available, is being ignored?

# Please explain why you are ignoring the findings of NEJM and JAMA that support the use of Evusheld in immunocompromised people?

# Please explain why you are ignoring the findings and strong recommendation of APPG that recommend the urgent use of Evusheld

# Why is the immunocompromised community being discriminated against by the application of higher governance thresholds that were not applied for the introductions of vaccines including the latest bivalent vaccines?

# How is that every single covid drug including the Moderna Spikevax was given a rapid trip through the procurement process via Rapid Cov19 leading to 2 conditional approvals by the MHRA. Evusheld did not receive any help pre full MHRA yet it could be a long-drawn process of over a year before it can be in use. Why?

# Please explain, that based on real extensive data and use in 34 nations, what is preventing NICE to give emergency approval for the use of Evusheld for the immunocompromised community before winter? Anything but the emergency approval would only mean that the immunocompromised are being severely discriminated against and that their lives don’t matter.

# Is NICE willing to have the avoidable deaths of 1000s on their hands? If not, please explain how quickly you will approve the use of Evusheld?

# Can you please publish all the data that you are analysing for Evusheld and make it available ASAP?

# Please explain why interim emergency use has not been approved for Evusheld ie why is it the ONLY covid treatment that has not been given emergency use approval? Who made the decision that it should not be given emergency approval and when was this decision made?

# I would like to understand why there has been such an extended period of acute absence of transparency and avoidance of truth about the decision-making around Evusheld in recent months. Finally, when it comes to analysing the cost-effectiveness of Evusheld, will you be assessing things like the potential 92% reduction in hospitalisations for Covid (data from Israel).

# Kindly guide us with your strategy to protect the immunosuppressed since vaccines have limited efficacy. It is challenging for mental health & overall health to continue shielding. With a lack of robust public health measures it is fearful to even access medical appointments. Evusheld is actively being used globally. Why would it not make sense to leverage this Great British innovation even if has just some benefit which can be life-saving .Thanks-have a lovely day

# 500,000 immunocompromised people are facing their 3rd winter shielding. If it is a matter of cost, please consider that all these people who have not been to concerts, museums, art galleries and restaurants would at last have the confidence to return to these activities and the subsequent benefit to the economy. If there is enough evidence of the efficacy of Evusheld for 32 other countries, why is England different?

# I’m very immunosuppressed & have had 5 Covid vaccines (I’m entitled to a 6th but can’t obtain one, as I can’t have mRNA vaccines). Has NICE carried out the public sector equality duty as part of the assessment into obtaining Evusheld? Why is NICE denying the human rights of those who are still having to shield? Our right to life; right to inhuman treatment; right to a private & family life, & the right to freedom from discrimination is being breached by Government & governmental bodies.

# Are there sub-group meetings focused on your progress on Evusheld that are also open to public? If so, where is there information on dates, booking, please?

# How many immunocompromised might die by the time you reinvent the wheel on Evusheld?

# Despite several calls for DHSC to publish the data you have analysed, you haven't. Please can you publish it and make available?

Based on the evidence and after careful analysis and consideration, the UK Government decided not to procure Evusheld for prevention through emergency routes at this time. This is a decision based on independent clinical advice by RAPID C-19, a multi-agency group, and a UK National Expert Policy Working Group and reflecting the epidemiological context and wider policies in the Government’s pandemic response and recovery. The Government has however referred Evusheld to NICE for evaluation through the technology appraisal programme.

NICE received the referral on 10 August 2022 and started the appraisal process at the end of August. The first committee discussion is planned for March 2023, with guidance likely to be issued for consultation in April 2023.

NICE does not have the ability to make recommendations for expedited or urgent use and is working as quickly as possible to complete the technology appraisal, including bringing forward the deadline for the company’s evidence submission so that it is able to issue guidance to the NHS as quickly as possible.

A summary that lists the evidence considered by the RAPID C-19 oversight group to assess whether Evusheld could be used to prevent COVID 19 would be shortly published on the NICE website (is now available: <https://www.nice.org.uk/Media/Default/About/what-we-do/covid-19/RAPID-C-19-summary-briefing-tixagevimab-and-cilgavimab-prophylaxis.docx>).