IN THE UK COVID-19 INQUIRY

MODULE 4

SUBMISSIONS ON BEHALF OF
CLINICALLY VULNERABLE FAMILIES ('CVF')
FOR THE FIRST PRELIMINARY HEARING ON 13th SEPTEMBER 2023

A. INTRODUCTION

1. These submissions are made on behalf of Clinically Vulnerable Families ('**CVF**'). On 17th July 2023 the Chair designated the group collectively as a Core Participant ('**CP'**) for Module 4 of the Inquiry, stating in her reasons that CVF:

> *"can assist the Inquiry in understanding individuals' experiences of accessing vaccines and therapeutics from the perspective of those considered to be clinically vulnerable and/or severely immunosuppressed."*

(i) A brief introduction to CVF

2. CVF represents a group of vulnerable individuals who have underlying conditions, many of whom are immunosuppressed, who are at high risk of severe outcomes from the disease, such as greater mortality (x9.2 more likely compared to those who are healthy[1]) and long covid (x5.4 more likely compared to those who are healthy[2]), than the greater population In many cases, they continue to shield to this day. For many vulnerable individuals, the pandemic is by no means over and indeed they still face as significant a risk – and in some respects a higher one, because of the removal of mitigation measures – from contracting Covid-19 as they did in early 2020.

[1] https://www.ons.gov.uk/file?uri=/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/preexistingconditionsofpeoplewhodiedduetocovid19englandandwales/quarter12023/deathsduetocovid19preexisitingconditionsq120231.xlsx (Table 1)

[2] https://www.ons.gov.uk/file?uri=/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/datasets/alldatarelatingtoprevalenceofongoingsymptomsfollowingcoronaviruscovid19infectionintheuk/30march2023/longcovid1920230330accessible.xlsx (Table 5)

3. CVF was founded in August 2020 and currently represents those who are Clinically Vulnerable, Clinically Extremely Vulnerable and the Severely Immunosuppressed, as well as their households, across all four nations. CVF initially concentrated on issues relating to education but very quickly broadened its focus to other issues such as healthcare, risk mitigation at work and the provision of accurate scientific information. CVF is a grassroots organisation; it is not a legal entity and it does not have charitable status.

4. CVF is keen to ensure that the Inquiry considers the full impact of the pandemic on the clinically vulnerable, the clinically extremely vulnerable 'the shielded', and the severely immunosuppressed, their families and households. Such individuals not only faced but continue to face greater risks to their lives than any other category of person. As such, any planning for future pandemics and/or consideration of the effectiveness of public health services needs to do so with the impact on the clinically vulnerable as a key group at the forefront of such planning. Moreover, mitigations are required now for new Covid-19 variants.

5. CVF looks forward to assisting the Inquiry regarding the issue of the vaccination and therapeutics of clinically vulnerable, clinically extremely vulnerable and severely immunosuppressed.

B. KEY AREAS OF FOCUS FOR CVF IN MODULE 4

(ii) Use of new therapeutics

6. Many of CVF's members are severely immune suppressed, such as from transplants, cancer, immune suppressing medications and immune deficiencies. CVF has a multitude of valuable case histories and thematic analyses on the access and use of new therapeutics. Through the pandemic the antivirals that were of sufficient efficacy against specific Covid-19 variants changed. CVF wish to bring the antiviral medication eligibility criteria and the omissions to the Inquiry's attention.

7. CVF can assist the Inquiry in the practical difficulties experienced by the clinically vulnerable relating to the communication of the process to obtain antivirals and the challenges within the pathway, both for vulnerable patients and staff.

8. CVF can also assist the Inquiry regarding the narrow list of people who are eligible for antivirals. Many people who are vulnerable to severe Covid-19 do not qualify for antivirals, for example diabetics, people with Chronic Obstructive Pulmonary Disease and older people. These people have sometimes, inconsistently, been pointed towards the Panoramic or Principle Trials (the Principle Trial has now ended). CVF are very concerned about these trials as they were using people with known vulnerabilities to a higher risk of more severe Covid-19 and only giving treatment to half. Some medications that were given were already proven not to be effective (e.g. Ivermectin).

9. CVF can assist the Inquiry with case studies where people were eligible for antivirals, tested positive on a lateral flow test, reported it on the Government portal and then received no contact from the NHS Covid-19 Medicines Delivery Unit ('**CMDU'**). Given the antivirals should be provided at the earliest opportunity and within 5 days, people are often then under pressure to obtain access, and urgently. CVF members report being continually 'looped' between 111, 119, GP surgeries and secondary/tertiary hospital clinicians, at each service being told to contract a different one or that it's not their job. Many clinicians managing vulnerable patients do not know the correct process. CVF have assisted some members during this pathway, often advocating at the eleventh hour, sometimes resolving matters through member's MPs. CVF can explain this to the Inquiry and the assistance that CVF have given their members in accessing antivirals.

(iii) Difficulties faced by the clinically vulnerable in accessing antiviral treatment in hospitals

10. CVF are keen to assist the Inquiry with the difficulties that the clinically vulnerable have faced in accessing antiviral treatment in hospitals for various reasons and issues with a lack of communication to both staff and patients on the available treatments once in hospital. This barrier to accessing treatment has not only likely prolonged recovery for numerous clinically vulnerable individuals but also left many others without any access to essential antivirals. CVF are concerned that vulnerable inpatients (who are admitted for non-Covid reasons) and who then develop nosocomial infection with Covid-19 are ineligible for antivirals. In addition, patients who are admitted but are still mild to moderate symptomatically to COVID-19, they also cannot access antivirals. CVF belief

this probably contributes to the high mortality burden (31%-35%) following nosocomial infection in vulnerable people in NHS hospitals.

(iv) Inequality and antivirals

11. CVF are concerned about matters relating to inequality and antivirals. The CMDU clinical decision maker has the final decision on whether someone can be prescribed antivirals. CVF have members who are eligible by their specified condition and whom have been referred by their GP, who are still refused treatment with antivirals. CVF are concerned that CMDUs do not make the same clinical decisions, creating a healthcare access inequality. CMDUs are generally not open on evenings, weekends and bank holidays, making the prescribing window of five days even more challenging. During Covid-19 variant peaks the service was busier and sometimes overwhelmed, resulting in patients being left untreated. CVF can provide evidence and case studies of this to the Inquiry.

12. The antiviral process itself is fraught with steps and complexity, many clinicians managing vulnerable patients do not know the correct process. CVF can assist the Inquiry in understanding how digital poverty and exclusion mean that some clinically vulnerable people did not, and still do not, have access to the internet and are unable to report their positive LFT online. In the beginning of the antiviral treatments, vulnerable people were sent PCRs to test themselves and return by post. CVF wants to highlight to the Inquiry the difficulties with this, the delays, lost samples or 'indeterminate' results, again delaying the antivirals pathway. CVF considers the move to reporting Covid-19 on LFT was positive, however issues remain.

13. Even patients who were prescribed the antiviral medication within the 5 days window, sometimes had access issues in terms of collecting their medicine. Often it was couriered directly to patients, but not always. CVF are aware of vulnerable and sick patients needing to use public transport to pick up their medication. Since antivirals were not approved for vulnerable children they were inconsistently prescribed 'off label'. CVF are concerned that this creates a potential inequality for vulnerable children.

14. Another new therapeutic that was developed by AstraZeneca during the pandemic was Evusheld, which helps to reduce the chances of infection and severity of Covid-19 in people who have had an unsatisfactory immunological response to Covid-19 vaccination, especially the severely immunosuppressed. The issue in the UK is that Evusheld was not treated equitably to the vaccine or antivirals with the process of rapid assessment, rather it was subjected to NICE approval. CVF is a stakeholder for the NICE process[3] for consideration of both antivirals and Evusheld to enable CVF to advocate for clinically vulnerable people.

15. CVF's view is that the lack of access to Evusheld in the UK has left severely immunosuppressed patients significantly unequal when compared to immune competent persons. This has meant that Evusheld was not available at any time from the NHS, unlike other OECD countries. Immunosuppressed people have not been given access to a prophylactic that would give them the same protection as someone who is successfully immunised. This has had substantial life-changing effects on CVF member's lives. They are often unable to partake in 'normal' life in the way that successfully vaccinated persons can. This has affected many areas such as work, education, and socialising. It can even affect the basic needs such as buying food, collecting medicine and attending medical appointments. CVF can assist the Inquiry on these points which only impacted upon the clinically vulnerable and their families, and a large number of their membership. CVF campaigned throughout 2022 on the licensing of Evusheld both to AstraZeneca, MPs and Parliamentarians. Through conversations with AstraZeneca, CVF achieved access for patients to visit Poland to receive Evusheld and subsequently, finally on the 19th October 2022 the private provision of Evusheld. CVF can assist the Inquiry on this and the impact of Evusheld being finally privately available from 19th October 2022. It was, and still is not, available on the NHS.

16. Consequent to the evolution of the virus, Evusheld became much less effective. Clinics were not set up to give Evusheld and CVF worked with various medical facilities to bring this prophylactic treatment, and then advise our membership of the pathway. The issue in the United Kingdom is that Evusheld was not treated equitably to the vaccine with the process of rapid assessment, rather it was subjected to NICE approval. CVF can assist the

[3] NICE are deciding on which groups will be eligible and which medications will be available on the NHS.

Inquiry with case studies of their members having to pay for it themselves privately (approximately £2,000 per dose per 6 months) with clear inequalities surrounding this. The delay in access meant that the window of time of it working was very short (around 2 months). Despite its inefficiency Evusheld is still available privately as the only option for all severely immunosuppressed people. Many of CVF's most vulnerable patients, including transplant patients[4], have not been able to purchase this drug. CVF are concerned that vulnerable severely immunosuppressed people in the UK have lost the opportunity of a safer 2022, particularly the immune suppressed group who have been mainly shielding now since March 2020.

(v) Treatment of the clinically vulnerable for Covid-19 in hospital

17. CVF's members have experienced issues relating to treatment in hospital with Covid-19. There appears to be a lack of communication to both staff and patients on the available treatments once in hospital. The antivirals discussed to date are those mainly on the 'outpatient, mild to moderate disease' pathway. As such, there is a lack of access to antiviral medication if inpatient in hospital as they are only available to outpatients. This appears to be even true if the patient was admitted for another reason, such as a broken leg with subsequent nosocomial Covid-19 infection. These vulnerable patients cannot access the antivirals they would if they had contracted it at home. CVF also has members who have been inpatients for the treatment of Covid-19. Often, it appears that the general medical staff are not aware of the options for inpatient COVID-19 treatments. Some of CVF members have had problems accessing treatments in hospital, therefore delaying their treatment and likely recovery.

(vi) Prioritisation and eligibility criteria for vaccination

18. CVF is concerned about the prioritisation and eligibility criteria for vaccination through the pandemic. There is evidence of inequality of access between geographical areas, for adults, children and their families. CVF have case studies of the challenges people faced accessing vaccinations either being turned away despite eligibility or lack of access in terms of availability.

[4] Annex 4

(vii) Barriers to vaccine uptake by the clinically vulnerable

19. Some CVF members have had to travel significant distances to vaccination centres. Many CVF members have found the centres unsafe for the clinically vulnerable, with some members even contracting Covid-19 as a consequence. CVF are concerned that some patients who are eligible for vaccination have not taking them up, as they remain concerned about the risks. In addition, vaccine damaged patients are concerned about further damage. The communication on vaccination is confusing and people do not understand their eligibility. The eligibility lists for antiviral medication and vaccination, such as the 'spring boosters' for example, are different.

20. Many clinically vulnerable adults live in households with children, some of whom were also clinically vulnerable. For them, speedy and safe vaccination was paramount. There were multiple issues affecting children's vaccination in the UK, including slowness of distribution in schools. The delays led to many more children contracting Covid-19. CVF are concerned that there was an apparent policy to encourage infection and delay vaccination. There is a clear inequality for the very youngest vulnerable children or vulnerable families with very young children. There are other issues to be discussed further such as the lack of support for people with allergies to vaccinations, or people who are vaccine hesitant.

C. SUBMISSIONS

(viii) The Provisional Outline of Scope

21. CVF appreciates that this is a provisional list, and is likely to be supplemented in due course by a list of issues. However, one point CVF wishes to highlight is that it appears that a significant proportion of the focus to date in this module has been on vaccinations rather than therapeutics: evidenced by the fact that only one of the six topics identified in the provisional scope relates to therapeutics, and that (as submitted below) none of the Key Lines of Enquiry for the listening exercise relates to therapeutics.

22. CVF submits that both topics – vaccinations and therapeutics – are of equal importance. It may be that the current disproportionate focus on vaccination is caused in part by the very

significant public focus on vaccinations during the pandemic. However, from a public health perspective, both are hugely important. CVF have set out, above, some provisional points it makes in relation to therapeutics which have been of central importance to the clinically vulnerable from the moment they were developed.

23. For these reasons, CVF respectfully requests that the Inquiry ensure that, going forward, Covid-19 therapeutics are given the appropriate level of prominence in Module 4 and are not lost in the (also important) consideration of Covid-19 vaccinations.

(ix) The proposed Key Lines of Enquiry ('KLOEs')

24. CVF agree with the proposed KLOEs at Counsel to the Inquiry's ('**CTI**') note para. 58(a to (c).

25. In answer to the questions set out at para. 60(a) to (c) of CTI's note:

26. CVF consider that the KLOEs at 58(c)(i), (ii) and (iii) are particularly important.

27. As to further topics, CVF propose the following
    a. As a general point, there is no reference to the development and use of new therapeutics during the pandemic in the KLOEs. This is an important element of Module 4 (see para. 2 of the Provisional Outline of Scope) and it should be included in the KLEOs.
    b. Consideration of children and/or parents of vulnerable children and/or families who are immunosuppressed living in the same household as clinically vulnerable children.
    c. Clinically vulnerable people who have vaccine priority status but who are not immunosuppressed (the topics only mention immunosuppressed not clinically vulnerable *per se*). For example, people over 65, some people with asthma, diabetes and other conditions which were defined as clinically vulnerable had the priority status for the vaccine and had access to vaccination earlier than the rest of their age group. They should be considered.
    d. The effect of Covid-19 vaccinations on other childhood vaccinations. For example, CVF considers there has been increased vaccine hesitancy due to mixed messaging

around children being vaccinated for Covid-19, meaning the rate of take-up of other vaccines like MMR has gone down

e. The vaccination of clinically vulnerable under 5s – they have been made to wait years compared with other countries for their vaccine and some families have travelled abroad to get their child vaccinated. CVF's members have found access to this vaccination is still met with barriers and many under 5s are still not vaccinated. There has been a severe lack of communication on process for both parents/guardians and primary healthcare staff. CVF are aware of parents of CV children who have been vaccinated abroad; their only option.

f. Healthy under 5s were not offered vaccination despite all other children and young people over 5s finally being offered them. CVF are aware of healthy under 5s who have been vaccinated abroad; they're only option. This means that all current primary school year 1 children have not been routinely offered covid vaccination. Additionally healthy under 5s living in families within the Clinically Vulnerable and especially immune suppressed family members have not been offered vaccination.

g. Those with sensory or learning disabilities should be included in the KLOE research, especially those in residential care homes for the under 65s as learning disabled died a lot more than others with Covid-19 and yet were not prioritised for the vaccine like other groups were.

h. In para. 58(a)(i), CVF proposes that the following underlined words are added: "*The key sources of vaccine-related information obtained by participants and/or their parents/guardians*".

i. In para. 59(b), CVF proposes that the following words are added: "*Ethnicity and/or religion".* This is important as some religious groups are wary of vaccinations[5] or for other reasons had a low uptake of Covid-19 vaccination[6].

D. CONCLUSION

28. CVF hope that these submissions are of assistance to the Chair.

[5] See e.g. https://lawandreligionuk.com/2022/09/13/religious-objections-to-covid-vaccine-wierowska/
[6] See e.g. https://blogs.lse.ac.uk/religionglobalsociety/2021/01/minority-reporting-on-vaccinations-who-are-the-priorities-and-the-dilemma-of-protection/

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