Witness Name: Clinically Vulnerable Families

Module 4

Statement No: 1

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IN THE PUBLIC INQUIRY INTO THE
COVID-19 PANDEMIC

WITNESS STATEMENT OF CLINICALLY VULNERABLE FAMILIES

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Clinically Vulnerable Families, will say as follows: -

1. This statement is prepared in response to the UK Covid-19 Inquiry's request dated 31 August 2023, for evidence under Rule 9 of the Inquiry Rules 2006 in respect of Module 4. This statement is prepared jointly on behalf of Clinically Vulnerable Families ("CVF") by Founder and Leader Mrs Lara Wong and by Deputy Leader, Dr Catherine Finnis. Throughout the statement case studies and quotes have been provided from many of CVF's members to assist the Inquiry in understanding their real life lived experience.

2. This statement has been jointly written with both signatories contributing to separate and distinct parts of the statement. If the Inquiry intends to call a representative of CVF to give oral evidence at the Module 4 hearings, Lara Wong and Dr Catherine Finnis respectfully request that they are permitted to give evidence together, or both be called as separate witnesses on behalf of CVF.

3. It is noted that for the purpose of this Rule 9 request, that the date range of the pandemic is set as the period between 30 January 2020 and 28 June 2022. Where we refer to the pandemic within this statement we do indeed refer to that prescribed time period. However, we do not agree that the pandemic came to an end on 28 June 2022. For many of our members the pandemic remains a very real and live issue, and in some cases still curtails their fundamental freedoms; it will likely remain that way unless real and immediate action is taken to improve their situation. We highlight throughout this statement, examples of our members lived experience but stress that those experiences did not get better on or after 28 June 2022, but instead remain the same in present day. We therefore respectfully urge the Chair to consider the impact on the pandemic upon the clinically vulnerable and their families during the defined period but to understand that for many, that lived experience is ever so present as it was during that time.

A Introduction to Clinically Vulnerable Families

4. CVF is a grassroots organisation; and until 16 October 2024 was not a legal entity. CVF was incorporated as a Community Interest Company[1] (a private company limited by guarantee) on 16 October 2024. It was founded in August 2020 before children returned to schools for the first time following their closure towards the start of the pandemic in late March 2020. At that time, parents were told that schools were safe and that all children must be in school. We were repeatedly told that children did not catch or spread

[1] Company Number 16022972

Covid-19 infections but despite that, CVF remained concerned due to the risks posed to clinically vulnerable staff and children in schools and to other clinically vulnerable close contacts living in households with children who were attending school. This was pre-vaccination.

5. Clinically extremely vulnerable persons had been shielded between 21 March 2020 and 1 August 2020, including many clinically vulnerable persons more informally. To these families, nothing had really changed in the pandemic; their unaddressed risks remained and consequently they felt exposed with limited options available to them or the protections in place to mitigate their vulnerability. For them, Covid-19 still represented a significant and serious threat to their lives and the health of their families and communities' wider connections.

6. After shielding was paused in April 2021 and never resumed, CVF extended the offer of support to all clinically vulnerable persons and those who could be considered at high risk by living in clinically vulnerable households, and therefore widened its membership and strategy to incorporate the many concerns and needs of all clinically vulnerable families in the UK.

7. CVF currently represents those who are Clinically Vulnerable, those identified as Clinically Extremely Vulnerable (before this terminology was retired) and the Severely Immunosuppressed, and those in their households, across all four nations. CVF initially concentrated on education but very quickly broadened its focus to other wide-ranging issues such as healthcare.

8. CVF's mission is to support, inform and advocate for those in clinically vulnerable households as they face an ongoing threat posed by Covid-19. Our vision is that one day we will have sufficient protections to restore the freedoms of society's most vulnerable.

9. CVF has multiple purposes, and these have evolved since its foundation. CVF primarily aims to support, educate, assist, advocate and campaign for clinically vulnerable families in the UK due to the risks posed by Covid-19. To further understand the work of the group we have set out how CVF fulfils its functions below:

a. **Support**

CVF's social media presence has grown and is firmly rooted in our four core principles:

(i) To be scientific and evidence based;

(ii) To provide peer support and practical assistance (i.e. drafting letters, helping with other correspondence and communications for our members);

(iii) To address the mental health needs of members by offering weekly check-ins with members; and

(iv) To operate exclusively for the clinically vulnerable and their households. Through communication with our members, CVF is able to identify and address any additional needs that arise from a member's circumstances, such as the need for legal advice and advocacy.

b. **Education**

Due to our backgrounds, the group is able to offer a variety of resources to help our members and actively share good quality scientific publications, with possible interpretations, to help assist members to access the information. This includes, but is not limited to, sharing how to assess individual risk and advice on how to reduce risk of Covid-19 infection; providing information on eligibility for additional vaccines and antiviral treatment including advice on any processes involved and commonly experienced difficulties; and regular updates on government policy documents relating to clinically vulnerable families.

c. **Assist**

CVF assists clinically vulnerable families in the following ways:

(i) CVF aims to identify those members with urgent needs and help them by offering peer support. For example, we have helped members access antiviral treatments within the tight timescales of 5 days by providing basic explanations of how to apply, as well as helping to make representations to members' MPs in some exceptionally challenging cases;

(ii) The group tries to support members who have been fined and/or prosecuted for Covid-19 related absences in school and those who are losing their jobs or being made redundant for Covid-19 related reasons;

(iii) CVF has supported people in making requests for risk assessments and reasonable adjustments within school and employment settings.

d. **Advocacy and Campaign**

CVF is working collaboratively with various other charities and organisations pursuing shared and unique goals. Our key issues include:

(i) Clean indoor air;

(ii) Reasonable adjustments in schools and in workplaces;

(iii) Improved access to treatments;

(iv) Removing barriers to living 'in' society through improving Covid-19 safety protections;

(v) Access to antivirals;

(vi) End to isolation rules;

(vii) Masks in schools;

(viii) Masks in healthcare;

(ix) Freedom Day concerns including mask wearing;

(x) Safe access to healthcare;

(xi) Inequalities for children forced out of schools;

(xii) Access to Covid-19 testing;

(xiii) Safe shopping / food deliveries;

(xiv) Raising awareness on behalf of Covid Orphans;

(xv) Job losses;

(xvi) Choice between education and lives;

(xvii) Stopping the spread (reducing transmission);

(xviii) Masked carriages on trains and buses;

(xix) Exam conditions risking infections;

(xx) Inequalities for clinically vulnerable families in exams;

(xxi) Pressure from school and education authorities on clinically vulnerable families which resulted in the removal of children from the school roll;

(xxii) The general need for reasonable adjustments for clinically vulnerable people;

(xxiii) Access to the National Tutoring Programme;

(xxiv) *"Ghost Children"*[2]

(xxv) Risks posed by warm rooms;

(xxvi) Access to Covid-19 prophylatics;

(xxvii) Access to private Covid-19 vaccines;

(xxviii) Against government adverts encouraging sick children to attend school;

[2] A name given by the Chair of the Education Select Committee, Robert Halfon MP, to describe children missing from education since the onset of the pandemic.

(xxix) Safe voting;

(xxx) Right to protest whilst masked;

(xxxi) The right for anyone to wear a mask; and

(xxxii) The recognition of Clinically Vulnerable as protected characteristics under the Equality Act with new and distinct needs.

10. In question 4 of the Rule 9 request the Inquiry asks for a summary of any formal engagement by CVF with UK government departments, the devolved administrations or other public bodies relating to the matters set out in the Provisional Outline for Scope of Module 4. Even though this is out of order, we consider it best to summarise our engagement here to help introduce CVF and what it has done and continues to do in this area. To date, CVF has driven policy change through various methods. CVF has:

a. Shared members' case studies with the local and national media;

b. Developed and maintained strong links with Parliamentarians who have asked questions in Parliament on behalf of CVF;

c. Taken part in relevant All-Party Parliamentary Groups ("APPGs"), for example, members of the group were invited to take part in the Coronavirus APPG chaired by Layla Moran. This led to a question being asked in the House of Commons about clinically vulnerable people and schools;

d. Joined forces with other campaign and educational groups, such as Covid-19 Bereaved Families for Justice, Independent SAGE (for example, in relation to 'The Covid-19 Pledge' where, as a signatory to the pledge, we have advocated for the needs of our members and have worked to raise awareness of the pledge directly with companies and by encouraging our members to raise with their employers and other businesses.), Clean Air Classrooms and Long Covid groups. CVF has brought its unique perspective to these collaborations, a perspective which is not available from any other organisation;

e. Made connections, established awareness, and raised CVF's profile through social media platforms, aiming always for a better future for the clinically vulnerable and their families;

f. CVF is a stakeholder of the National Institute for Health and Care Excellence ("NICE") appraisal for Evusheld and has gathered information to contribute to their recent call for evidence. The submissions made by CVF to NICE are set out in more detail at **[Exhibit LWCF/01 - INQ000408806]**. CVF have been involved in various other appraisals, not just for Evusheld, such as:

Antivirals :
Casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 [ID4038]

Remdesivir and tixagevimab plus cilgavimab for treating COVID-19 [ID6261]

Prophylaxis :
Tixagevimab plus cilgavimab for preventing COVID-19 [ID6136]

AZD-3152 for preventing COVID-19 [ID6282]

11. More information about the group and the work that we do can be found by accessing CVF's website, images of which can be found at **[Exhibit LWCF/02 - INQ000408817]**.

B. CVF Membership: Clinically Vulnerable, Clinically Extremely Vulnerable People (including the Severely Immune Suppressed)

12. The names of these groups were created by the government during the pandemic, along with the term 'shielding'. These terms have continued to be removed and changed by the government over the period of the pandemic to the current day. Although the term, Clinically Extremely Vulnerable ("CEV"), has stopped being used by the Government, many who were designated CEV continue to describe themselves as such.

13. The term Clinically Vulnerable ('CV') remains in active use today. It covers all of those who remain at higher clinical risk to Covid-19 and qualify for vaccines based on those risks. The UK Health Security Agency's "Covid-19: Green book, Chapter 14a" **[Exhibit LWCF/03 - INQ000408795] p20** states:

"Those clinically vulnerable to COVID-19 are defined by the JCVI priority groups as:

a) children of any age with severe neuro-disability, severe or profound and multiple learning disabilities (including Down's syndrome and those on the learning disability register) or immunosuppression (as defined in table 4);

b) adults who have underlying health conditions leading to greater risk of disease or mortality as defined in table 3; and

c) those of advanced age."

14. It is difficult to calculate how many people in the UK these groups now cover and how many CV people in the UK qualify for vaccines, however, we do know that:

    a. In March 2022, The State of Ageing 2022 Summary by the Centre for Ageing Better **[Exhibit LWCF/04 - INQ000408850]** estimated that 19% of the population were aged 65 and over. Therefore, for those clinically vulnerable due to age (aged 65 and over) the figure is almost 11 million people.
    b. A report published by NICE, *'Tixagevimab plus cilgavimab for preventing Covid-19',* on 14 June 2023, has calculated the number of severely immunosuppressed people eligible for Evusheld is 1.8 million **[Exhibit LWCF/05 – INQ000339319]**. Over the period of the pandemic, the various government lists of CEV/CV and Severely Immunosuppressed have been added to. Some people are not aware of their status.
    c. As stated by the BBC News, 'England on track for vaccinating Covid priority groups' dated 12 February 2021 **[Exhibit LWCF/06 - INQ000408872]**, the total number of persons identified in the top priority groups in 2020/2021, excluding care home workers, health and social care workers, and those aged 64 and under, but including those aged 16-64 with underlying health conditions, totalled approximately 20.5 million. It is important to note that these figures exclude CV young people under the age of 16.

15. As reported in the Lancet, '*Changes in Covid-19 related mortality across key demographic and clinical subgroups in England from 2020 to 2022: a retrospective cohort study using the OpenSAFELY platform', Lancet Public Health 2023; 8:e364-77, Nab L et al* **[Exhibit LWCF/07 – INQ000420565]** and the BMJ, *'Risk prediction of Covid-19 related death or hospital admission in adults testing positive for SARS-CoV-2 infection during the omicron wave in England (QCOVID4): cohort study', BMJ 2023;381:e07296, Hippisley-Cox J et al* **[Exhibit LWCF/08 – INQ000420566]**, these groups have always been at highest risk of poorer outcomes from Covid-19 infection and continue to be into the fourth year of the pandemic, despite vaccination This is especially true for immune suppressed individuals, who may not mount a response to Covid-19 vaccination and therefore have no obvious protection from Covid-19 as set out in *'Impact of Covid-19 on immunocompromised populations during the Omicron era: insights from the observational population-based INFORM study' The Lancet Regional Health – Europe 2023;35: 100747, October 2023 Rachael A Evans et al* **[LWCF/09 – INQ000420567]**.

16. Table 1 of the final Office of National Statistics ("ONS") dataset indicates that people who have 'underlying conditions' versus 'healthy people' have 9.2 times increase in death from Covid-19 **[LWCF/10 - INQ000408875]**. Table 5 of the same dataset indicates that people who identify as 'activity limited a lot by health conditions' versus 'healthy people' have 5.4 times increase in developing Long Covid **[LWCF/11 - INQ000408796].**

17. CVF was forged from these new groups of people created by the government during the pandemic. Shielding had never happened to people, this was a totally new experience. Neither had being grouped into national categories designating your vulnerability to a virus.

18. Our support group is limited exclusively to those in clinically vulnerable households. Entry questions are used to determine whether applicants to the group meet the criteria as outlined in "Covid-19: the green book, chapter 14a"[3] **[LWCF/03 - INQ000408795]** (or those with household members who have qualifying conditions). At present, the combined membership and following of CVF is approximately at 49,098 and is continuing to grow. The group have a significant online presence, through which most of their work is achieved. As at the date of the drafting of this statement, there are 2,556 members of CVF's private Facebook group, 13,235 followers on Twitter (now known as X), and 1,166 Mastodon followers. Each member or follower tends to represent a family or household and we can therefore reasonably assume that CVF's reach is at least three times the number of actual members and followers to account for multiple occupancy households.

C. Overview of CVF's Concerns in relation to Module 4 Issues

a. Vaccine delivery programmes and prioritisation decisions

19. CVF is concerned that some people, despite being eligible according to the NHS lists were/are not invited for vaccination. From the start of the vaccination process this has caused, and continues to cause, a lot of distress and confusion, and the person often then must spend many hours trying to sort it out, just to enable them to access a vaccine.

[3] Current at the time the statement was written but has since been continually updated

Quote 1 from CVF Member

"My husband is supposed to be red flagged for vaccinations. He hasn't once been called by our GP, not even for 'flu jabs, when others with no health issues, have. They can't explain their system."

Norma, aged 75 (present day)

20. Many of the issues around that first vaccination appear to have been where people were not automatically called for vaccination, and that was mainly as they had not been recorded CEV or that the coding had not worked and they were not called.

Quote 2 from CVF Member

"My GP didn't record me as CEV until much later and kept questioning whether I was. I had to send email evidence and ask them to read my neurologist letters repeatedly. My mum and dad are paid and unpaid carers, both living with and caring for me which I am still unsure if that has been recorded properly. In the end we just kept trying on the national booking system and whoever became eligible first, can't remember who it was, it has been different every time, booked and then we all went and explained the situation and the clinicians were fine with it and made us feel really comfortable although it was still scary because the uncertainty of eligibility was scary and because it was the first outing we had with lots of other people but looking back it was probably the safest because everyone was masked and distanced and it was well ventilated."

Karen, aged early 30s

21. We know from members within CVF that many people at high risk of Covid-19 infection felt that they had a high risk of becoming infected with Covid-19 during vaccination in vaccination hubs. **[Exhibit LWCF/12 - INQ000408864]**.

22. People often reported early vaccine hubs as being over-crowded, and not properly distanced. In recent times, with subsequent vaccination booster offers, there has been a dilution or complete removal, of all protective measures. There is often now inconsistent or absent mask wearing. Some geographical areas have no staff or patients wearing masks, whilst others are still asking staff and patients to mask.

23. Since May 2023 and the Spring Booster Campaign, most areas are now no longer masking and people at high risk of Covid-19, and especially the Severely Immunosuppressed, who are the exact people who need to access vaccination, feel they are being put at additional risk. There is often no requirement for staff or patients

to mask with FFP2 / 3 respirator masks or enhanced ventilation and air filtration with HEPA. Communication was and continues to be poor, and some people who are eligible for vaccination chose, and continue to choose, not to be vaccinated due to the risks of catching Covid-19, with clear potential negative consequences for this high-risk group.

24. In the initial vaccination campaign in early 2021, it was apparent that some geographical areas were much slower than others. [**Exhibit LWCF/13 – INQ000408865**] Some shielded people had to travel a substantial distance in order to receive a vaccination. One of our members had to travel over 140 miles in a round trip in January 2021 whilst still shielded to be able to access a vaccine. This created additional stress and transport issues, and clear inequalities.

25. Many CV/CEV and Severely Immunosuppressed people have various underlying conditions and medication that can interact with vaccinations. Some people are unable to take the vaccination due to previous anaphylaxis to vaccination and this leaves them in a very precarious position. These people need a prophylactic treatment such as Evusheld in addition to as many non-pharmaceutical protections as possible, especially in indoor settings, such as healthcare, education and workplaces.

26. Since the start of the vaccination programme there has not been very much information available to people about which vaccination is available, where and when. This can make it difficult for people to book.

27. One of the greatest difficulties with the vaccination programme for CVF has been the changes to the eligibility criteria. The data [*set out in further detail at paragraphs 57 – 60*] shows that some people who are at higher risk of mortality and severe illness, such as diabetics, hypertensives etc are not eligible for vaccination in some booster campaigns, meaning they only have boosters less often and when immunity may have waned. The experience of our members tells us that people who are severely immunosuppressed are concerned that their family members who live with them, cannot always access booster vaccinations.

<u>The First Covid-19 Vaccination Experience</u>

28. The first vaccination occurred in the NHS when Margaret Keenan became the first person to receive the Pfizer Covid-19 jab on 8 December 2020. For many CEV people who were still shielding and for many then CV people this offered the first opportunity to

see a way through. At this time no one in the country knew how much immune response they may have to the Covid-19 vaccination and there did seem to be a general belief that it would be transmission blocking, in other words that it would mean that once vaccinated you could neither catch nor transmit Covid-19 to anyone else. This was very significant for the clinically vulnerable as they are very much at risk from other people who are carrying the virus particularly those in their homes, workplaces, social occasions and importantly in healthcare settings.

29. For many CV and CEV people their first vaccination experience at the end of 2020 or the beginning of January 2021 represented the first time they had been outside their houses for nearly a year. This was understandably very frightening and the experience was very nerve wracking, yet most of our members report that they made their way to the vaccine centre when they were called. Generally, CVF members found that on arrival at their vaccine centre, which was most commonly a mass vaccination centre, they found that it was very well ordered, that everyone was masked, and there was no fight to be vaccinated.

Quote 3 from CVF Member

"My first one was the easiest, I got called up to go to the Excel Centre in London, by my transplant consultant. They were expecting us, everyone was masked, there were short queues and it was all very organised. They did both my husband and myself. We had to sit for 15 minutes, then went home. The second shot was similar but everyone after that has been much more difficult."

Julie Barrable, aged 60

30. Despite there being a feeling from CVF members that generally the first vaccination experience in the mass vaccination centres was a good one (and the least stressful, especially in terms of Covid-19 risk of infection), there are definitely some issues that we would like to raise. Some CVF members found that their first vaccination experience was very frightening as often the vaccination centres were very busy with many, many people and certainly many more people than they had seen in the previous 10 months. For those who had been shielding, this was often the first time they had been outside their house at all since March 2020. There was also the issue with other patients constantly removing their masks, particularly after they have had their vaccination to eat and drink for example whilst waiting the 15 minutes until they could leave. CVF believe that even though the first vaccination experience was generally the least risky in retrospect, there should have been better Infection Prevention and Control measures

("IPC"). **[Exhibit LWCF/12 - INQ000408864]**. CVF suggest that there should have been clear guidance in all vaccination centres that mask removal was not permitted. Drive through vaccination centres could have been prioritised for CV people and advertised as such.

Quote 4 from CVF Member

"After I had my Pfizer Covid-19 vaccination at a mass vaccination centre, I was invited to a separate area which was laid out with seats quite close together to my surprise. There I was offered a cup of tea or coffee and biscuits, a nice touch but I was concerned about the removal of masks. There was no obvious ventilation and so I decided that I would not accept their offer of refreshment and I kept my FFP3 mask on the whole time."

Maria, aged 39

31. Indeed, some people were perplexed that staff members continued to remove their masks to chat, eat and drink.

Quote 5 from CVF Member

"First vaccine was in hospital setting – very scary as was very busy, masks constantly being removed. Waiting room was packed, staff removing masks to chat, eat and drink. No windows or doors open – I left without waiting 15 minutes and waited outside instead as felt unsafe."

Vicky, aged 51

32. As Vicky's quote shows there are some people who decided that the risk was too great and did not wait the required 15 minutes.

33. In the early days of the first vaccinations, vaccinations were often only recorded manually on cards and in records. For some people this caused an issue as those records were then not updated in a timely manner.

Quote 6 from CVF Member

"My only observation is that all our vaccinations were manually recorded to later be uploaded to the main NHS database. My second vaccination a few months later was a little more frustrating as the database hadn't been updated by then and my records took a little while to be found. In my experience once I managed to get on the system I eventually received a notification to book a booster jab even though it often arrived after I had already booked and had it myself."

Ken Baker, aged 67

34. There were many different methods of even mass vaccination centres at the time. With some of them even described as drive through. Generally, CEV and CV people report 'drive through' as a very positive experience as they do not have to go into a large hall with many other people many of whom, especially nowadays are not wearing masks. They can feel at particularly great risk during these experiences.

Quote 7 from CVF Member

"First one was great, that was the drive thru one but I drive and I live in a city"

Anon Member

35. For some people their first jabs were even at their GP surgeries. It felt as though there was definitely some sort of postcode lottery with some people being required to travel many miles as we have already explained and some people being able to access their first vaccinations early on in GP surgeries.

Quote 8 from CVF Member

"The first one was the best, like all my subsequent jabs it was at the GPs. Everyone masked, marshals monitoring distancing in the queue etc"

Catherine, aged 57

Quote 9 from CVF Member

"I received a text from my GP saying I was to get my vaccine the day and time had already been made and it was to be at another local GP practice because my GP practice didn't do the vaccines. I was told in the text that because I am immunosuppressed and I was at high risk to covid I was going before my age group. The surgery is 3 miles away so not far, I went in the car, everyone was in masks, social distancing and temperature taking and hand gel given by staff on the door. They only allowed so many in at once and it was a good experience all in all. I was actually surprised to get the notification, my GP has been a nightmare since the start of covid and not noticing that I am immunosuppressed."

Jill, aged 64

36. Overall, that first vaccination experience was full of promise and often people, particularly CEV people and people who had been shielded, felt so relieved to get it. They believed that this heralded a new sense of freedom, a time when they would be

able to reconnect with their family and friends that they had not been able to see for the preceding 10 months.

Quote 10 from CVF Member

"I was so relieved to get it, I remember my eyes filling with tears."

Helen, aged 45

Quote 11 from CVF Member

"Fantastic! It was step towards being able to live with my family again."

Suzanne, aged 60

37. Communication gaps were evident regarding the time it takes for vaccines to become effective and the importance of receiving multiple doses to strengthen the level of protection. In a December 2020 interview on Sky News, an elderly gentleman shared his excitement about reuniting with family on the very day he received his first vaccine dose, unaware that its protective effects would take a couple of weeks to build and that it would not provide the full protection from the complete course until he was doubly vaccinated, and there was no promise of sterilizing immunity. Thankfully the reporter, who understood some of the risks, gently discouraged him. CVF is concerned that newly single vaccinated vulnerable elderly people, may have been at greater risk as a consequence especially during Christmas gatherings permitted under the rules which allowed three household bubbles to mix, unless Tier 4 restrictions were in place.

Vaccination Boosters

38. For many people there have been issues in getting boosters, not least because the criteria for boosters keeps changing. Indeed, even the age for boosters keeps changing, as clearly set out in Annex A. Also, whether somebody is able to be boosted because they live in a household with someone who is immunosuppressed or not appears to be changeable depending on the individual booster programme. This makes it very difficult indeed for people who are vulnerable to follow these complicated rules. It has also been difficult at certain points for people to describe and prove their vulnerability. Often there are complex groupings within the Green Book and people cannot be expected to follow and understand these. For example, people who have rare diseases (which as a group are fairly common) are often not specified *per se,* within the Green Book, which can create vaccine eligibility access issues for these people. For newly diagnosed people, it was a very mixed picture, according to CVF's membership: some were informed that

they could now access additional boosters, or indeed, antivirals, but some were not. Generally, the public do not know about the 'Green Book' and rely on other information, such as the NHS website. This was often quite hard to find during the pandemic and still continues into the present. Often there has been very little advice available either from people's consultants in hospital or indeed their GPs.

Quote 12 from CVF Member

"Access has been the real issue, my GP doesn't do covid boosters and I never get invited for them, even though I'm eligible. Each one has been a fight to find out what is going on and when I can book one and I have had to take the initiative and book them myself online."

Juliet, aged 60

39. For many people it is necessary to book their Covid-19 vaccine through the national booking site. This site can be very complicated for someone who is not used to or unable to manage a digital platform. Indeed, it even asks you what your NHS number is and as many people do not know what this is, this could put people off.

40. There was also the issue around communications from central government. We are not experts on this but CVF's members' experiences showed that there was confusion around the third primary vaccination for immune suppressed people and there was a paucity of information on how to book a third primary vaccination. Often it really depended on the clinically vulnerable person's understanding of the situation, interaction with media, interaction with other groups such as CVF, whether or not they were aware of a booster campaign.

Eligibility for Boosters

41. The eligibility for boosters has changed often over the course of the pandemic and is reported by some CVF members to be confusing. In addition, a different set of people are often eligible for the Covid-19 booster to the influenza booster. This creates confusion both within clinically vulnerable people and healthcare workers. Often for people who are left off the eligibility list, or for whom their specific rare condition is not mentioned, it very much depends on the GP whether or not they are able and willing to sign them up to the vaccine campaign. This opens up an inequity, particularly for people who have severe conditions that are not recognised within the eligibility groups or for

people for have rare conditions where their specific condition is not specified within the eligibility groups.

Quote 13 from CVF Member

"*I only qualify for autumn boosters as a carer for my learning disabled son who also qualifies but neither of us qualify for spring boosters so only getting them yearly. So when we all caught Covid in March I was very unwell because I am asthmatic but I don't qualify through being asthmatic.*"

Karen, aged 50

Quote 14 from CVF Member

"I have chronic asthma and take five medications daily to keep it under control. Every year pre Covid I would catch colds and need courses of high dose oral steroids and antibiotics to get my breathing back under control. As I have taken precautions during the pandemic I have not had any viruses since then and therefore haven't needed oral steroids. This means I don't meet the JCVI criteria for poorly controlled asthma. However I went to my GP in 2021 with details of many studies showing that Covid makes asthma worse and explained that being self-employed and not wanting to be a burden on the NHS or society and thankfully, he agreed to use his discretion and added the high risk coding to my file. I was therefore able to get a booster in autumn 2021 and was invited again in 2022 and this year THAT IS ONLY because I have a sensible GP that I am offered continued protection."

Jo, aged 47

42. There were some people who fell into booster campaigns simply on age and yet they also had an underlying condition that did not make them eligible should the age range change. For example, the CVF member below was over 50 years old so could access a vaccine in the Autumn 2022 campaign, on age alone. However, by 2023, the age threshold was raised to 65 years and she, with Chronic Fatigue Syndrome ("CFS"), did not qualify by medical condition nor age, so could not access a booster. However, some GPs will support people with non-eligible conditions such as CFS to access a autumn booster.

Quote 15 from CVF Member

"I am aged 50 plus so didn't have to worry about eligibility in 2022. Good job I was over 50 as with CFS I am not sure I would have been eligible in 2022. I went to a walk in clinic in October 2022 for my booster. It was very well organised, busy but every single person in a mask, they were being handed out at the door. The queue moved quickly in and out

in a few minutes and it felt safe. In contrast my son became eligible for a booster in December 2022 after his 16th birthday so I took him to a different walk in clinic, long wait, waiting room was packed, not enough seats and a minority of people wearing masks, when I asked for the door to be left open for ventilation I was told no because there was no heating. I did not feel safe. I am concerned about eligibility for this autumn and having to write to my doctor to see if I might be able to access a booster."
Kim, aged 52

Quote 16 from CVF Member
"As with a large number of asthmatics I wasn't eligible for the booster as I hadn't needed oral steroids in the last few years due to taking extra precautions since 2020 and not catching the usual colds and viruses which usually result in chest infections. I got the booster only after registering as a carer for my father who has MND and lives with us."
Vicky, aged 44

The Third Primary Vaccination

43. The third primary vaccination was offered to people who were immunosuppressed eight weeks after their second vaccinations. Most people, including most CV or CEV people, were only offered a two-dose primary course but the third dose was shown to be a vital addition to boost the immunity of those who may have had poor responses to their initial vaccines. For some people the third primary vaccine ran into the autumn booster of 2021, therefore meaning they had a delayed autumn booster sometimes running through the whole of that winter.

44. There were many issues around the access to the third primary. Many members of CVF were initially unaware, due to a lack of messaging, that they were eligible for the third primary vaccinations and there was often no information on how to access this dose. Letters were sent late, by which time some people had already received a standard booster.

45. You were not able to book on the national booking site as there was no option for a third primary, only a booster. Immunosuppressed people also had problems as it did not seem widely known within healthcare staff at that time that some people were entitled to a third primary vaccination. There was also very little information for people, particularly who were on the immunosuppressant, when the best time to take this third primary might be.

46. CVF members report that they often spent a lot of time contacting their GP to see whether it could be arranged or attending a mass vaccination centre with documentation. In terms of the documentation, it was not straightforward to understand what kind of documentation CV or CEV people needed. The NHS issued general shielding letters, alongside specific clinical letters from hospital consultants. However, confusion arose as the shielded group did not align with the severely immunosuppressed group, leading to misunderstandings among both patients and healthcare workers. People were frequently confused which letter they needed to take and so frequently they were turned down at the vaccine centre either because they did not have the right documentation or because the centre simply did not know about the third primary vaccination for immunosuppressed people. In response to these challenges, CVF encouraged our members to carry comprehensive evidence, such as prescriptions, medical letters, and even medicine boxes.

47. CVF members also found that the computer system was not designed to record the additional dose. Members reported that their previous vaccination data was sometimes overwritten, or the information was stored in a non-standard manner, and often it was not recorded at all. How it was recorded varied from one data entry person to the next. Red warnings frequently appeared, notifying vaccinators that they could not administer a dose within six months of the previous one, even though, the third primary should have been offered with an 8-week gap.

48. The incorrect recording of these doses then led to the inadvertent offering of booster doses sooner than the recommended 6-month interval **[LWCF/14 - INQ000420572]**. Many individuals would not have fully understood this information, potentially resulting in them receiving booster doses at the incorrect time, due to persistent reminder text messages and emails highlighting the importance of booster doses.

49. Following their struggle to access a third primary vaccine, one member reached out to the regional vaccine enquires team for guidance on recording a booster dose, as the third primary had been incorrectly categorised as a booster (the nurse had confusingly said it was a 'third booster'). The vaccine enquiry team directed them to the national data resolution team via the 119 service. CVF encouraged our members to go through this process as it seemed that responsibility fell on individuals to both identify and pursue corrections to errors in the system. CVF are concerned that the majority of people simply would not have realised.

Quote 17 from CVF Member

"I found it very difficult to get the booster vaccine third primary dose. I rang my GP a number of times they hadn't heard of it. Also my consultant and nurse specialist had no idea, I emailed the info that was on the NHS website saying give people who are eligible the vaccine to both GP and consultant but still no joy. I printed the green book information about the vaccines sent to consultant, took it in by hand to GP and still no joy. I got told to come back to pick up the paperwork from the GP that we took in, it had a note on saying 'nothing to do with them'! When info was coming on the TV and media I rang the GP again and was told I don't know what I am talking about from the receptionist. After a week and reading and hearing so many getting the vaccine booster I tried the GP nurse specialist helpline again and the nurse helpline said they are getting a lot of phone calls about this and haven't yet decided how to move forward. I was told to ring in a week I rang again and they were still deciding what to do. I rang again the next week and I was told the paperwork was being sent out. I waited another two weeks, rang again to be told still getting paperwork done and I should get the paperwork in the next two weeks. I got the information on day 12 of the 14 days I then had to email only, no phone number was given, the vaccine centre and wait for a response. I waited 10 days and nothing, emailed again and got a response saying I had an appointment at the big vaccine hub in 5 days' time. All extremely frustrating, annoying, upsetting and I was sadly treated very badly by my GP, especially the receptionist."

Jill, aged 64

Quote 18 from CVF Member

"The third primary dose was a nightmare. I made countless phone calls to the GP having to argue long and hard with receptionists who didn't know anything or were telling me I had to wait 12 weeks for a booster, the number of times I had to keep repeating 'it is not a booster' was ludicrous. I eventually wrote to my GP himself and received a call from the practice manager to my complaint. I was told I needed a letter from my renal consultant to book I must bring it to the jab appointment. I have known my consultant for years and have his personal email so I emailed him. He was aware of the third primary dose but didn't know about the letter, what it needed to contain and who should be responsible for writing it. In his words 'you know far more about it than we do'. He was cross at the level of inaction in the unit, other trusts have got letters out to their patients.

After a fairly substantial number of further emails and also liaising with his secretary I eventually managed to get a letter emailed to me. Therefore I could not book the third

dose, I took the letter along with me and not a soul asked to see it! All this delayed my third dose considerably to late October, it was some weeks after most have got it. It was distressing and incredibly frustrating, I spent many hours phoning and emailing."
Catharine, aged 57

Quote 19 from CVF Member
"My GP has been pretty useless the whole way through. I am CEV due to being on immunosuppressant medication following heart transplant. After a few frustrating conversations I took the initiative and sorted my vaccinations myself. The whole covid situation has also highlighted a big problem with the quality of clinical coding in general practice."
Anon Member

b. Barriers to uptake of the vaccine and disparities in vaccine coverage between identifiable groups

Distance

50. One issue that many CV and CEV people faced in relation to the first vaccination, and indeed subsequently, has been the distance required to travel to the vaccination centre. This was particularly when the vaccination was first rolled out; often, to receive the Pfizer vaccine, you had to go to a centre as the vaccination had to be stored at a very cold temperature, which meant the facility needed to have a fridge. Many people living in rural or even semi-rural or smaller towns had to travel to larger cities to go to larger hospitals who were mass vaccination centre. This was particularly problematic for people who do not drive.

Quote 20 from CVF Member
"As a non-driver in a semi-rural area, I found it very difficult to get my first vaccine. I had to wait for my daughter to be free to be able to take me. When I discussed the issue with my GP surgery, I was told that it would be ok to travel for nearly an hour on a crowded bus to get the vaccine as 'you can't covid on a bus!"
Julie, aged 57

51. Even for drivers sometimes the distance required to drive was immense: for one of our members they needed to drive a 160 mile round trip to be able to access their first vaccination.

Quote 21 from CVF Member

"I was lucky as my husband drives and therefore I was able to get to the mass vaccination centre in London. I dread to think what would have happened had I not been a driver as I would have had to gotten on several trains and buses to be able to get there."

Katie, aged 40

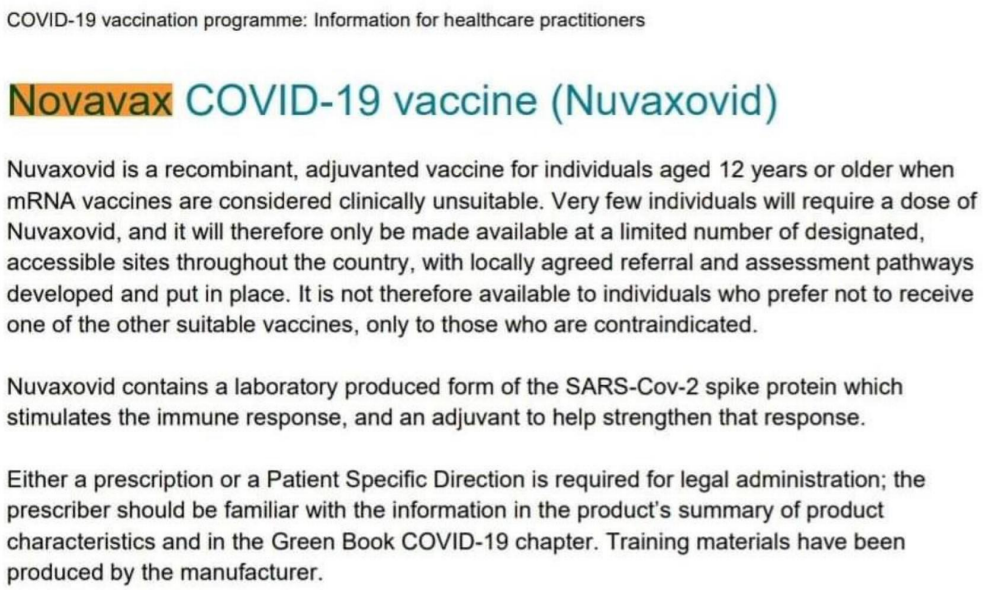
Allergy

52. There are various groups of people who for different reasons cannot have a specific type of Covid-19 vaccine. Quite early on it was discovered that the AstraZeneca vaccine had the potential to cause thrombocytopenia and blood clots in some people. For people who have a thrombophilia, that is underlying conditions that make their blood clot more easily such as Antiphospholipid Syndrome (sticky blood) or Factor V Leiden, they did not receive any advice. This made people quite concerned to get the vaccine who had these underlying conditions as they were unclear whether this could make their condition worse. It was not until those initial first vaccines were given to vulnerable people that the instruction changed on AstraZeneca and it was no longer given to people who had an underlying thrombophilia.

53. There were also people who subsequently had reactions to Moderna or Pfizer and these people required a specific vaccination when they attended a vaccine centre. Due to the lack of accessible communication with vaccine centres (there was no way for people to communicate directly with the vaccine centre by telephone, email or text) it was often difficult if not impossible to establish which vaccine would be available at what time. Indeed, the government campaign instructions told people to just accept whichever vaccine they were offered. However, this is not possible for people who have an allergy or bad reaction to a previous vaccine and who have been advised to have a different one.

54. Specialist vaccines such as Novavax and Sanofi were purchased, we assume by the government, for people who could be more likely to have adverse reactions to other vaccine types, but clinically vulnerable people with allergies often had prolonged waits, had to travel greater distances and frequently had to self-advocate. Different areas had different protocols which lead to further inequity. A UK Health Security Agency information document, "*Covid-19 vaccination programme: Information for healthcare providers*" version 6, republished on 3 May 2023 **[LWCF/15 - INQ000390078]** indicated

that Novavax would only be made available at a limited number of designated sites throughout the country, as can be seen in in the extract below at figure 1:



COVID-19 vaccination programme: Information for healthcare practitioners

Novavax COVID-19 vaccine (Nuvaxovid)

Nuvaxovid is a recombinant, adjuvanted vaccine for individuals aged 12 years or older when mRNA vaccines are considered clinically unsuitable. Very few individuals will require a dose of Nuvaxovid, and it will therefore only be made available at a limited number of designated, accessible sites throughout the country, with locally agreed referral and assessment pathways developed and put in place. It is not therefore available to individuals who prefer not to receive one of the other suitable vaccines, only to those who are contraindicated.

Nuvaxovid contains a laboratory produced form of the SARS-Cov-2 spike protein which stimulates the immune response, and an adjuvant to help strengthen that response.

Either a prescription or a Patient Specific Direction is required for legal administration; the prescriber should be familiar with the information in the product's summary of product characteristics and in the Green Book COVID-19 chapter. Training materials have been produced by the manufacturer.

Figure 1 – Exhibit 15, page 15

Quote 22 from CVF Member

"Main issue has been for a family member who has had a bad reaction to Moderna but not Pfizer. More recently they removed the choice at the clinic and she needed to get a specific patient directive but getting one was a major challenge as there was only a pathway for allergies. Luckily I had contacts in the Scottish government and highlighted the list which has now been corrected and they found lots of patients in a similar situation."

Peter, aged 50

Quote 23 from a CVF Member

Struggled to find Pfizer rather than Moderna. I expect a similar struggle this year. Two family members had bad reactions to Moderna (one serious with Pleurisy and then lasting lung damage) and also research from ME groups so fewer patients with ME seriously affected by Pfizer. The system has no capacity it seems for acknowledging this or enabling choice of which vaccine someone can get even when there are sound medical reasons for it. Unless you personally have had a severe reaction and doctors have recorded it you are just expected to get whatever happens to be there the day you

book for. In France they offer choice to everyone including Novavax. We would have much better uptake if that were the case here.

Lots with ME celebrated the approval of Novavax and had waited to get it after seeing the numbers with ME made long term worse by Astra Zeneca and MNRA but we have never been given that option. Many remain unvaxxed as a result. Lack of choice and a refusal to accept issues with current jabs for some patient groups in particular leads to lack of protection for many.
Anon Member

c. Trials exploring new therapeutics and the effectiveness of existing medications in treating Covid-19

d. Access therapeutics

Eligibility

55. CVF is of the view that the list of people eligible for therapeutics has always been and continues to be particularly limited, especially given the underlying conditions and age profile of people admitted to hospital and sadly dying of Covid-19. We would welcome an increase in the categories of those eligible for antivirals. As per the NICE appraisal (ID6262: Nirmatrelvir plus ritonavir for treating COVID-19 (Partial Rapid Review of TA878)) **[Exhibit LWCF/01 – INQ000408806]** we would strongly support the roll out to these groups of people, in addition to those already eligible:

- Aged 70 years and over;
- With a body mass index (BMI) of 35 kg/m2 or more;
- With diabetes; and
- With heart failure.

56. The eligibility criteria for antivirals were yet another 'list' of conditions, different again to the previous vaccine priority lists or the third primary vaccine eligibility. CVF members were frequently confused and assumed that being previously identified as CEV was sufficient to qualify for antiviral treatments. As a consequence, a 'pinned' post was added to the top of the group, with the full list of qualifying conditions and treatments to enable members to check for eligibility. Even to this day, it often comes as a shock to people

when they test positive only to find that treatments that they assumed might have been available to them were tightly restricted.

57. The current eligibility for antivirals is set out in paragraph 60 below. However, there have been changes to the eligibility criteria since antivirals became available, often confusing healthcare staff and patients. Many previously CEV and CV are still excluded from accessing them but would benefit from being offered them. There were two important papers by Professor Iain McInnes (Chair of the Covid-19 Neutralising Monoclonal Antibodies (nMABs) and Antivirals Access Independent Advisory Group) and John Edmunds (London School of Hygiene and Tropical Medicine) which have fed into the assessment by NICE.

58. In late 2021, at the request of Professor Jonathan Van Tam (the former Deputy Chief Medical Officer) an advisory group was constituted to identify a set of patient conditions (or cohorts) that were deemed to be at the very highest risk of an adverse Covid outcome, namely hospitalisation and death. Their Independent Report, *'Defining the highest risk clinical subgroups upon community infection with SARS-Cov-2 when considering the use of neutralising monoconal antibodies (nMABs) and antiviral drugs (updated March 2023)', McInnes I et al, updated 19 September 2023* **[Exhibit LWCF/16 – INQ000420574]** concluded that some people have a health condition that may increase their risk of getting seriously ill from Covid-19, such as, those with the following health conditions which collectively are estimated to affect about 2 million people:

- Down's syndrome
- Certain types of cancer including leukaemia
- Certain conditions affecting the blood, such as sickle cell disease
- People who have had a stem cell transplant
- Kidney disease
- Liver disease
- People who have had an organ transplant
- Conditions affecting the immune system, such as HIV or AIDS, inflammatory conditions, or immunodeficiency conditions affecting the brain or nerves (MS, motor neurone disease, Huntingdon's Disease)

59. The government website makes clear that in Winter 2022, the Covid-19 Antivirals and Therapeutics Taskforce was planning for the potential wider deployment of antivirals against Covid-19, should there be new evidence of the drugs'

effectiveness in a wider cohort. As part of this work, the Therapeutics Clinical Review Panel was required to consider whether there are further high-risk patient groups that could benefit from antiviral treatment – in particular, whether there are groups that have a risk that is at least as high as those that are already eligible for treatment. The Therapeutics Clinical Review Panel Independent report chaired by Edmunds, *'TCRP modelling group findings: risk of severe Covid-19 outcomes' published 31 March 2023* **[Exhibit LWCF/17 – INQ000420575]** showed that patient groups including those who are aged over 79, diabetic or obese constitute more than 10 million people and used a different methodology to McInnes, using diagnosis codes to identify people with certain conditions. The groups in the Edmunds study were likely to be heterogenous and include a significant proportion of people with much lower risk. CVF agree with NICE and Edmunds that the additional broader groups need to be added to the antivirals access list.

60. The *Covid-19: guidance for people whose immune systems mean they are at higher risk – last updated 13 November 2023* **[Exhibit LWCF/18 – INQ000420576],** which only applies to people living in England, lists the following eligible conditions enabling those people to access treatments, although it is not exhaustive:

- Down's syndrome, or another chromosomal disorder that affects their immune system
- certain types of cancer or have received treatment for certain types of cancer
- sickle cell disease
- certain conditions affecting their blood
- chronic kidney disease (CKD) stage 4 or 5
- severe liver disease
- had an organ transplant
- certain autoimmune or inflammatory conditions (such as rheumatoid arthritis or inflammatory bowel disease)
- HIV or AIDS and have a weakened immune system
- a condition affecting their immune system
- a condition affecting the brain or nervous system, such as multiple sclerosis, muscular dystrophy, motor neurone disease, myasthenia gravis, Huntington's disease, Parkinson's disease or certain types of dementia
- certain lung conditions or treatments for lung conditions

61. CVF consider that the above list of those who are eligible is too narrow and welcome the broadening for the group to include other CV people.

62. However, an important additional point is that currently the antiviral pathway is fraught with access issues and barriers even for the current smaller number of eligible people. A recent move away from NHS England commissioning to Integrated Care Board commissioning and access through GPs has severely hampered the process This will be discussed more later in this statement.

63. The Covid-19 Medical Decision Units ("CMDUs") were set up as a commissioned service to provide a clinical assessment of people who were potentially eligible. However, the assessment process had various significant issues, for example:

    a. People eligible on paper due to their condition were denied access at the assessment stage. Also, there were those that were unable to be referred for treatment (either no one would or could refer). CVF knows that many people who are eligible for antivirals struggle to get access to it within the required 5-day window for treatment. Often no one knows who to contact within the health service to obtain the medication. Often the GP refers to 119, 119 refers to 111 and 111 refers to 119 or back to the GP. This is something that continues to happen. Some patients did not know how to register a positive test online or do not have access to the internet, or the digital 'know-how'. This creates health inequalities in access to antivirals as there is not an equivalent phone number to call to notify someone you have a positive test. CVF has supported many people who have reported their LFT but then hear nothing. They are already feeling unwell, and the onus is then on them to 'chase' it up. Previously, people were referred directly to the CMDU where a clinical decision was made to decide if the person was now eligible. We know this is the case because lots of people within CVF have reported problems with the pathway. For example, some people who were eligible as per the NHS England Antiviral eligibility list were not found to be eligible at the clinical decision point for a variety of reasons, either because the decision maker did not believe the illness really qualified people as higher risk or because the person was not exhibiting sufficiently severe symptoms that in their view did not make them eligible for antivirals. This is despite the guidance for antivirals being clear that they should be given to eligible people at a mild/moderate stage of disease. This can leave people perplexed and confused, and without treatment.

b. Additional barriers were faced by eligible children.

Quote 24 from CVF Member

Despite all our best efforts our daughter tested positive for Covid for the first time late Dec 2022. As an immunocompromised child she was eligible for antivirals - she had recently turned 12 but I seem to remember there was a problem as she is light-for-age so the dose had to be altered.

In order to access these we had to contact her consultant, who in turn had to ring the regional childrens hospital (Bristol) and had to 'argue her case' . It was finally agreed and she attended our local hospital for consecutive days of IV infusions.

This was only possible because we have such a good relationship with an outstanding paediatrician - nobody on the phone lines or our GP surgery had any idea how to help us.

Anne, 50

c. People have received no response from the CMDU, and so have not been able to access the assessment for treatment.

d. People have experienced delays for assessment. Often the CMDUs are not open at weekends or on bank holidays which was a huge concern during long bank holiday periods over Easter or Christmas. This can eat into the five-day pathway quite a lot resulting in many patients falling outside of the timeframe by the time they were referred. It is also known that the earlier you can access the antivirals the better.

e. In many cases, there have been examples where eligible patients have been denied treatment reducing their likelihood of a good recovery.

Quote 25 from CVF Member

My dad Michael was diagnosed with Chronic Lymphocytic Leukaemia (CLL) in April 2021. He underwent chemotherapy and in January 2022, reached remission and the plan was for him to return to work and normal life later that year. In early February, he caught COVID. We all understood that his immune system was compromised due to his condition and the chemo he'd been treated with, so very quickly began making phone calls in an attempt to obtain anti-virals, which we understood to be available to people in just his kind of circumstances.

My mum first called 119, to get through to the CMDU, but found a message saying they were too busy. She called dad's haematology department, where an on-call haematologist explained anti-virals weren't required unless he became "very unwell."

Although initially dad's symptoms did not appear particularly worse than my mum's or anyone else we knew that had had COVID, he seemed unable to clear the infection. Over the course of the next few months, he was admitted and discharged from hospital twice before being re-admitted a final time in May 2022.

After some time in ICU, his body seemed unable to cope with the constant demands COVID had placed on it, and his oxygen requirements only grew. It was eventually realised that there was nothing else that could be done for him, and he sadly died on 4th June 2022.
Chelsea Warren, 30

f. During Covid-19 infection prevalence peaks, the CMDUs could become overloaded with patients, who were then untreated or who started their treatment later than ideal. Some providers, presumably due to the high numbers of patients, especially during 'waves' of Covid-19 have changed the 'window of treatment' to seven rather than five days. CVF is concerned this is not the best possible clinical protocol for patients.

g. More recently, on 27 June 2023, there was a change in commissioning and eligible people who caught Covid-19 were now required to contact their GP practice, NHS 111 or hospital specialist as demonstrated by an email sent to a CVF member **[Exhibit LWCF/19 – INQ000420577]**. In effect, this added a step to the process as people now need to try and communicate with these healthcare professionals rather than recording their result on a website and being contacted directly by the CMDU. One of CVF's members' concerns is that trying to get an appointment with a GP within the tight timeline and then being correctly referred for an assessment is very challenging, and in some cases, impossible through lack of access to primary care. CVF do not believe that this process is fit for purpose and suggest that the Inquiry needs to explore the access for people to antivirals. CVF also suggest the Inquiry could ask the NHS what proportion of people have tried to access antivirals but have failed to be prescribed them. CVF have many anecdotal reports of this being the case from our members.

64. Initially, to access the antiviral treatment, it was necessary for the people who were designated on 'the list' to complete the emergency PCR test they had been sent. This added an additional layer of complexity as it was often difficult to get the test done, posted and a result all within the five days. Quite quickly it was changed to a positive

Lateral Flow Test ("LFT"). People eligible for Covid-19 treatments can order LFTs online but only for their own use. This is so they can access treatment.

65. There were multiple issues:

    a. People struggled to do the PCR test correctly.

    b. PCRs could take a long time to be reported on, delaying the assessment for antivirals, and therefore the treatment.

    c. PCRs could be reported as inconclusive leaving people with the option to repeat the test, but then miss the 'window' of opportunity to access antiviral treatments.

66. Later, LFTs could be used but still there remained issues:

    a. People were confused where to report these (it had to be on a government webpage).

    b. Not all positive tests were automatically 'picked up' by the CMDU leaving people unsure what to do to get referred for assessment.

    c. LFTs are also technique dependent, complicated by the fact that some LFTs required mouth swabs, whereas others required nose and mouth.

    d. Some brands of LFT are more accurate than others and, as a consequence, CVF members sometimes bought their own. However, the NHS reporting website only accepted NHS distributed tests and not shop bought ones. This also posed a problem to people who may have been away from home at the time of their positive test and had to purchase a test.

67. LFTs were originally free to order by everyone, then the eligibility reduced to the vulnerable people (and others such as health and social care workers). However, this was not extended to their family or household members. This gave the impression that it was only CV people who needed to test and that was only so they could, at least in theory, access antiviral treatment. However, this was not how CV people felt. Most of them were not reassured by having treatments out there, especially as it was becoming known they were not easy to access. There was, and still is, clear government guidance that gives recommendations to persons at higher risk of Covid-19 and suggests that CV

people ask their visitors to test before visiting them **[Exhibit LWCF/18 – INQ000420576]**. They even cannot use their free LFTs for their carers to test. Most CV people still felt their best chance of reducing morbidity and mortality relied on reducing the chances of them being infected with SARS-Cov-2 and developing Covid-19. However, the burden was now firmly on the CV person to provide the other family members or other visitors with tests. This often meant purchasing them, as the free tests were only for the sole purpose of testing the CV person.

Emergency Antiviral Prescription (held by patients)

68. Eligible patients have no ability to have antivirals 'in advance' e.g., for a risky activity such as an inpatient hospital admission or for a holiday. This means they are often worried to be admitted to hospital as they would not be able to have them in advance. This is in an inequality as it means CEV people and especially the Severely Immunosuppressed often do not feel able to access hospital treatment as the rest of the population, save for access to antivirals.

Communication to Clinically Vulnerable People Regarding Antiviral Treatment

69. Generally, it can be said that the communication from the government to the persons decided to be at risk, was poor. People were very confused and were not all contacted at the same time. The communication to patients throughout for antivirals has been poor; it has been complicated, confusing and conflicting. Added to the constant changing of eligibility groups means people are very confused.

70. CVF supported its members by creating a flow diagram **[Exhibit LWCF/20 – INQ000420578]**, and also a post with country specific guidance **[Exhibit LWCF/21 – INQ000420579]**, to help people navigate the complex process to access antivirals.

71. Here are two case studies that further demonstrate some of our members' experience:

CVF Member B – Example of influencing access to antivirals

It became apparent through the group that people were struggling to get their antivirals within the critical 5 day window. Through internal analysis of cases we were able to establish that there were several barriers along the pathway.

1. Having to wait for a postal PCR to be processed, rather than using a positive lateral flow test (LFT).

2. Contacting the GP

3. Referral to the Covid Medicines Delivery Unit (CMDU) to assess

4. Waiting for a call back from CMDU

We were able to influence points 1 and 2. In terms of 1 we recommended that LFTs were accepted in place of PCRs. This was accepted shortly thereafter. For 2. We were able to influence the NHS to design a form that sits within the e-consult system which enables high risk patients to inform their GP of a positive LFT electronically therefore reducing the phone barrier whilst people felt unwell. It also reduces the time for this step within the critical 5 day window. There was an alert put on the e-consult system to enable the GP to see that an urgent request for antivirals had been logged and to enable them to prioritise that referral.

CVF Member M – Case Study

“M” was 58 years old when he was first diagnosed with a blood cancer, chronic lymphocytic leukaemia (CLL). He was reassured however that, although his condition required chemotherapy, it was very treatable. A plan was made for a six-month regime of IV and oral chemotherapy, after which it was expected that he would be able to return to his work as a social worker for kids in a residential setting, and life as normal.

His family understood that both his condition, and the chemotherapy to treat it, put ”M” at increased risk from covid. Having found information that blood cancer patients were less likely to produce antibodies to the covid vaccines, his daughter purchased an at-home antibody test kit which found he had indeed not developed an immune response. However, “M” was an otherwise very healthy and fit man; he chose to be careful in light of this information - wearing masks in public places such as shops, and for the most part avoiding busy restaurants for example - but he didn’t wish to isolate himself.

At the end of January 2022, ”M” finished his course of chemotherapy. He posed for a picture with the cancer nurses “ringing the bell” to mark the end of his treatment. Nineteen days later, he tested positive for covid.

His family were concerned given their knowledge of his vulnerability. They understood that clinically extremely vulnerable patients like him were eligible for antiviral treatments given within the first five days of testing positive, as a prophylactic measure to reduce the severity of their symptoms. Immediately they began researching means of contacting somebody to ensure he received the recommended treatments. The 111 service was “too busy” and the automated message told callers to find answers to their queries online. One call to the out of hours line for “M”’s local haematology department, led to them being informed that he did not require antiviral treatments unless he became “very unwell”. The 119 line informed them that should his PCR test be positive, his status as CEV would automatically be flagged up and ”M” would be called to assess his eligibility for prophylactic treatment.

The following day the PCR test did indeed return as positive, and as promised “M” received a call from the local CMDU shortly after. By this time his partner had also tested positive, and the both of them were feeling quite unwell with flu-like symptoms of coughs, aches and tiredness. ”M” was asked by the CMDU how he was feeling; being a typical stoic man, and believing that his symptoms - rubbish as he felt - were no worse than an especially bad cold or flu, his answer was that he didn’t feel too bad. For this reason, he was informed that it was not necessary that he receive treatment at that time. He did receive follow-up calls in the subsequent days - his symptoms appeared to be easing and so, as he was ascertained to be “improving”, again he was advised antiviral treatment was unnecessary.

Over the following weeks ”M”’s condition waxed and waned. For the most part, his symptoms were still mild to moderate, but by early March he was experiencing more and more significant bouts of breathlessness. He was admitted to the hospital for the first time in early March, where he spent five days being treated for pneumonia. After discharge, he failed to improve at home, and was re-admitted a little over a week later for a further five days.

Another couple of weeks later again “M” returned to hospital, and this time spent two weeks hospitalised. He improved significantly during this stay, and on discharge felt very well, but within a couple of days found it incredibly difficult to even use the stairs, and the pulse oximeter he was provided gave oxygen saturation readings in the low 80s, which are remarkably lower than a usual, healthy, reading. “M” returned to A&E to be admitted for the fourth and, it would turn out, final time, on 11th May.

It was during this time that it quite quickly became apparent that “M”’s condition was quite serious. By this time, a multi-disciplinary team of medics was discussing his case frequently.

A week after his admission he was sent to ICU where he was put on CPAP and, initially, his condition improved. After returning to the main ward however he deteriorated again and returned to ICU. Different treatments with very limited evidence of their use in such instances were implemented, including sotrovimab (a monoclonal antibody usually used prophylactically shortly after a positive covid test result), antivirals, and immunoglobulins.

Unfortunately, despite the best efforts of the medical teams, on the 1st June "M" and his family were told by medics that there was nothing more that could be done. Mechanical ventilation was deemed not to be in "M"'s interests as his lungs were damaged beyond repair and even if he survived, would be dependant on invasive oxygenation permanently. After withdrawing medications and oxygen on the 4th June 2022, "M" passed away with his family present in ICU.

Covid-19 Preventative Treatments (Evusheld)

72. Evusheld is a prophylactic treatment for Covid-19 composed of monoclonal antibodies that can protect people at higher risk of Covid-19 and especially those who have had a poor response to vaccination.

73. The Medicines and Healthcare products Regulatory Agency ("MHRA") approved Evusheld as a safe and effective treatment considerably later than other comparable countries, on 17 March 2022 **[Exhibit LWCF/22 – INQ000420580]**. The USA, for example, approved it and made it available under emergency use in December 2021 **[Exhibit LWCF/23 – INQ000420581]**. But in the UK, despite MHRA approval, which was accompanied by a positive sounding announcement on the government website (see figure 2 below and **[Exhibit LWCF/22 – INQ000420580])**, it did not result in subsequent NHS procurement. However, unlike vaccination, it was decided in the UK not to expedite the decision to allow Evusheld to be used as detailed within *The Long Shot: The Inside Story of the Race to Vaccinate,* by Kate Bingham & Tim Hames, published 20 October 2020, page 178 to 179 **[Exhibit LWCF/24 - INQ000408867]**.

Dr June Raine, MHRA Chief Executive said:

"After a careful review of the data, I am pleased to confirm that we have authorised another medicine to help protect against the effects of COVID-19.

"Evusheld is a "pre-exposure prophylaxis" treatment, meaning it is taken to prevent COVID-19 before the risk of acquiring infection. One dose has been found to provide long-lasting protection against this disease for up to 6 months.

"While the COVID-19 vaccines continue to be the first-line defence against COVID-19, we know that some people may not respond adequately to these vaccines and for a small number of individuals COVID-19 vaccines may not be recommended for other reasons, such as a previous allergic reaction to one of the vaccine ingredients.

"For these people, Evusheld could provide effective protection against COVID-19."

Figure 2

74. Decisionmakers treated Evusheld exceptionally, when compared to other Covid-19 pharmaceuticals, by subjecting it to the additional scrutiny of the NICE process which was initiated when the Department of Health and Social Care ("DHSC") made its formal referral on 10 August 2022. Concerns were later raised that Evusheld was not efficacious enough against Omicron, however, at the time of MHRA approval wild type ("WT") vaccines were still being administered.

75. We registered as stakeholders in this process and provided valuable data on the numerous and severe impacts experienced by this high-risk population. The extended period of 'shielding,' which our members have experienced frequently lacked any government support after CEV status withdrawal (and outside designated shielding periods), has led to substantial financial, educational, and health (both mental and physical) consequences, as well as significant social impacts.

76. Many CVF members have written to government ministers on this issue and one of our key members also started a government petition, which received almost 19,000 signatures **[Exhibit LWCF/25 – INQ000420583]**.

77. CVF have spoken to a number of opposition politicians about this topic but struggled to engage with Conservative ministers. In the 5-year period between 30/01/2019 and 30/01/2024, there were 44 references to Evusheld in Hansard **[Exhibit LWCF/26 – INQ000420584]**. There was also a Parliamentary debate on 12 October 2022 on the "Procurement of Evusheld" **[Exhibit LWCF/27 – INQ000420585]**.

78. The NICE appraisal was expedited and concluded on 6 October 2022, whereby the decision was made "not to procure Evusheld" **[Exhibit LWCF/28 – INQ000283336]**. Yet, in the USA, despite concerns, they doubled the dose to 600mg to improve protection **[Exhibit LWCF/29 – INQ000420587]** and subsequently approval remained in place until January 2023 – allowing USA citizens a year of freedom that we feel was denied to their UK equivalents.

79. Over 30 countries, including the USA, Germany, Poland and France made Evusheld available to their citizens.

80. People who are Severely Immunosuppressed who have not had a satisfactory response to Covid-19 vaccination are eligible for Evusheld. However, in the UK it was never been provided on the NHS.

81. CVF believed that AstraZeneca had the capability to make this crucial prophylactic treatment available. After numerous conversations, during which our founder Lara Wong advocated for private treatment options, including the possibility of seeking treatment abroad (given the growing trend of international travel for vaccines), AstraZeneca provided a phone number on 14 October 2022. This number allowed interested patients to access treatment in Poland with a referral from their UK consultant. The demand was so substantial that members reported that the phone line had crashed.

82. The following week, on 19 October 2022, AstraZeneca made contact with CVF to inform us that private treatment would be made available.

83. CVF members have had to travel internationally to access doses of Evusheld, including journeys to the USA by plane. This poses heightened risks, given the necessity to unmask for airport passport checks and potentially for eating and drinking.

84. Travel to access treatment was essential within the UK, as it was initially available in only a small number of locations. However, Evusheld is an expense that very few could afford. Some CVF members resorted to borrowing money, while others received financial support from friends and family. Unfortunately, the vast majority were left wanting.

85. Many Severely Immunosuppressed feel completely let down unable to access this treatment, affecting every area of their lives. They still feel 'stuck' in 2020, when the whole country has otherwise 'moved on'.

86. Despite the decision to withdraw Evusheld in other countries, such as the USA, the UK has continued to allow it to be offered privately to patients. CVF are concerned about this, as it may not be efficacious and may be offering expensive 'false hope' to immune suppressed individuals. It may even lead them to take undue risks thinking they have adequate protection having taken it.

87. Following the withdrawal of Evusheld in the US some people, whose immune systems put them at increased risk, decided not to purchase further doses of Evusheld. Others, however, will have continued to purchase it and perhaps will have taken greater risks as a result.

Quote 26 from CVF Member

"Partner and I both immunocompromised and don't respond to vaccines. Feel totally abandoned and also playing Russian Roulette with hospital appointments trying to second guess whether or not getting treatment and tests is more dangerous than potentially getting Covid. Pick your poison. Daughter turns 18 tomorrow. We've spent 3 years shielding from her in our home so she can lead a relatively normal life. Heart-breaking for u all. Worse thing is apparently seeing kind, rational friends and colleagues skipping along to the government tune that Covid is over."

Sally, aged 55

Quote 27 from CVF Member

"Initially I felt safe and protected when restrictions lifted, I felt abandoned and unsupported especially as I am part of the cohort that cannot respond to vaccination. When Evusheld was approved by MHRA, I was elated but devastated afterwards when I realised that NICE hadn't yet approved it. I still feel let down, ignored and dismissed. There are insufficient guidelines for employers and also for our hospital consultants. I had an infusion today and chatting to the ward sister about Evusheld etc she said about half of her former shielded patients are still shielding and she can see their mental decline." (May 2023)

Melanie, aged 53

Clinical Trials

SuperNova Trial

88. Following the rejection of Evusheld by NICE, AstraZeneca announced on 6 September 2022 that they would be trialling a new, updated, version of the drug whilst continuing to engage with the NICE appraisals process **[Exhibit LWCF/30 – INQ000420588]**. CVF became stakeholders in this subsequent process.

89. AstraZeneca recruited patients, many of whom are members of CVF, for this trial. The NICE process has yet to report its findings.

90. CVF lacks confidence in the government to make a different decision regarding funding Evusheld. CVF believes this treatment should not have been singled out for special consideration, and the same emergency rapid approvals used for vaccination should have been applied. This would ensure parity for severely immunosuppressed individuals, enabling them to regain lost freedoms similar to those enjoyed by the healthy population.

Quote 28 from CVF Member

"I joined the Supernova trial in August at Manchester because after over 3 years of shielding as CEV I wanted to volunteer to help myself and other vulnerable people to find some protection to enable us to return to society . I caught covid in September and very quickly became ill, my GP and 111 couldn't help with antivirals and I ended up in A&E because my vital signs were so bad but within 24 they had returned to normal (no antivirals taken) I believe that this is because of Supernova."

Mike, aged 54

Panoramic Trial

91. The Panoramic Trial was announced on 8 December 2021 initially as a trial for the antiviral Molnupiravir using clinically vulnerable, or those who were aged 50 years and over, Covid positive participants and to date is has recruited over 29,171[4] patients across 65 sites **[LWCF/31 – INQ000470343].** Their website describes the trial as follows:

[4] Accurate as at 30.01.2024

"Panoramic is a UK-wide clinical study sponsored by the University of Oxford and funded by the National Institute for Health and Care Research to find out in which people new antiviral treatments for COVID-19 in the community reduce the need for hospital admission and get better sooner."

92. CVF members who did not otherwise qualify for access to antiviral treatments were often directed to this trial as it was their opportunity to receive treatment. Up to 450 participants were accepted per day, half of which (225) were allocated to the treatment arm and the other half were not given anything outside of standard NHS treatment. Both groups had to record diaries.

93. CVF members raised several concerns regarding this trial:

a. **Limited to Working Hours.** The trial's operational hours restricted accessibility, being available only on working days, thereby preventing individuals from accessing treatment on weekends or Bank Holidays, as indicated by figure 3 below, a screenshot taken on 14 April 2022 from the Panoramic Trial website:

Figure 3

b. **Inadequate Capacity during Peaks.** During infection peaks, surges in demand resulted in fewer available slots for individuals in need of treatment, compromising timely access.

c. **Selective Treatment Offers.** Only 50% of accepted participants were offered treatments, yet patients with similar conditions in other countries, including the USA, were able to access treatment.

d. **Single Treatment Only.** Patients were only permitted to participating in the trial only once.

e. **Geographical Inequalities**. CVF noted in July 2022 that the Panoramic trial had changed its registration process, which restricted access to treatments to those with a participating GP as seen in figure 4 below, a screenshot taken from the Panoramic Trial website:

Figure 4

This introduced a potential source of inequality. People living in areas where GPs are not participating were effectively being denied the opportunity for treatment, as they could only access the non-treatment arm of the trial.

f. **Concerns over Eligibility Criteria**. The Panoramic trial included all high-risk patients (as seen in figure 5 below, taken from the Panoramic Trial website), even those eligible for antiviral treatments due to severe immunosuppression. This led to some individuals receiving trial invitations, as shown in figure 6 below showing a text message received by a member of CVF, instead of being directed for immediate treatment. This confused CVF members. CVF are concerned that this meant that those who should have been treated by the NHS faced a 50% chance of not receiving the vital treatment they required.

Figure 5

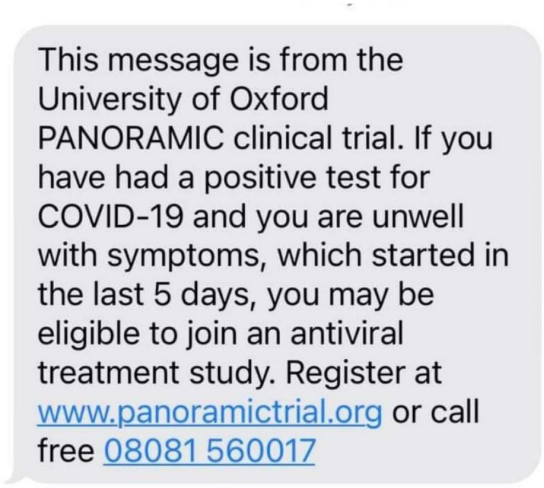


Figure 6

Quote 29 from CVF Member

I was denied antivirals for Covid after testing positive in December 2021. My GP told me I was ineligible and refused to refer me, despite this being incorrect as I am a transplant patient and I repeatedly had sent them guidance confirming my eligibility. My transplant consultant told me it was not their remit and that they were unable to refer despite my GP telling me otherwise. 111 advised that I contact my GP and the centre responsible for my being immunosuppressed (i.e. the transplant centre). After a few days of being sent in circles, I managed to enrol myself in the Panoramic trial, however I was not sent an antiviral that I could take as it [Paxlovid] was contraindicated for me and so I opted out of taking it after I had received it and only partially completed by follow up diary entries for them, due to severe fatigue.

Alex, 25

94. In December 2022, results published in the Lancet showed that Molnupirivir did not reduce hospitalisation and death against the Covid-19 variants at that time, however it did lead to a reduced recovery time and reduced viral load **[LWCF/32 – INQ000470344]**. Subsequently, the Nuffield Department of Primary Care Health Sciences announced in April 2022 that Paxlovid had been added to the Panoramic trial **[LWCF/33 - INQ000470345]**.

95. CVF believe that relying on a clinical trial as the primary route of care, without immediate access to treatment for vulnerable individuals raises concerns about prioritising research over public health. Sajid Javid's tweet, shown in figure 7 below, indicated that this trial was seen as part of the standard healthcare offered to NHS patients.

Figure 7, screenshot from social media 'X' formerly 'Twitter'

Quote 30 from CVF Member

"I was grateful to play my part in the University of Oxford Molnupiravir antiviral trial. I took the antivirals during my first week of my initial Covid illness back in February 2022. Of course I have no knowledge as to whether it contributed to reduced severity of my acute illness, but I am happy that I contributed. Two weeks later I had a pulmonary embolism and I still experience Long Covid symptoms; we will never know how things would have played-out for me if I hadn't taken Molnupiravir. This illustrates how it has been for us all during this on-going pandemic, clutching at straws."

Ben, aged 50

Quote 31 from CVF Member

"So shortly after I reported my test result I got an email saying I am eligible for antivirals as part of a national study, due to being CV and testing positive on lft. The trial antivirals have to be started within 5 days of the positive test.

Great news - I feel awful, I'm concerned about how my body will manage the virus, and obviously I want to recover as fast as possible, plus I literally just tested positive today so I'm well within their time frame.

Click the link and a message appears saying they're closed for the bh weekend! Which means I won't be able to access the antivirals as by the time they re open it will be day 5 at the earliest! 🤯🤦‍♀️

Absolutely gutted, and feeling frustrated at my bad luck with timing as well as my bad luck with a less than healthy body :/"
Sacha, 39 (Posted to CVF Facebook group. Dated 14/4/22)

Principle Trial

96. The Principle Trial started in March 2020 to trial Covid-19 treatments at home. It trialled various potential treatments including: Hydrochloroquine, Azithromycin and Doxycycline, Budesonide, Colchicine, Favipiravir and Ivermectin. People who were clinically vulnerable or experiencing shortness of breath due to Covid-19, aged 65 and above, were eligible to participate in this trial. According to the Nuffield Department of Primary Care Health Sciences, the trial had recruited almost 12,000 participants before it closed **[Exhibit LWCF/34 - INQ000470346]** in particular it said:

> *"Launching in March 2020, PRINCIPLE has grown to become the world's largest Covid-19 treatments trial for recovery at home in the UK, and possibly globally. Evidence from the trial has shown that the common antibiotics azithromycin and doxycycline are not generally effective treatments for Covid-19, changing clinical practice in the UK and abroad"*

97. CVF had serious concerns about the Principle Trial and did not recommend it to members. After Ivermectin was added we actively discouraged members from joining this trial:

a. By the time CVF was alert to the existence of the Principle Trial it was evident that many of the treatments lacked supporting evidence or had evidence against, raising considerable concerns.

b. CVF were troubled by the fact that some vulnerable patients were advised to access treatment on this trial through their GP practices, as it appeared to lend credibility to the trial despite the unproven evidence, or evidence against many of the treatments.

c. The study accepted both vaccinated and unvaccinated patients and there were concerns that they had not separated them for analysis.

d. Patients were recruited to this study for up to 15 days after their symptoms had begun. This meant the trial would have included both patients suffering severe symptoms and in need of other treatments, such as corticosteroids, and also others who may have fully recovered.

e. By the time Ivermectin was added to the trial in June 2021 there was substantial evidence against it as a treatment for Covid-19.

98. The website for the Principle Trial sets out the timeline of trial between March 2020 and April 2022, as shown in figure 8 below.

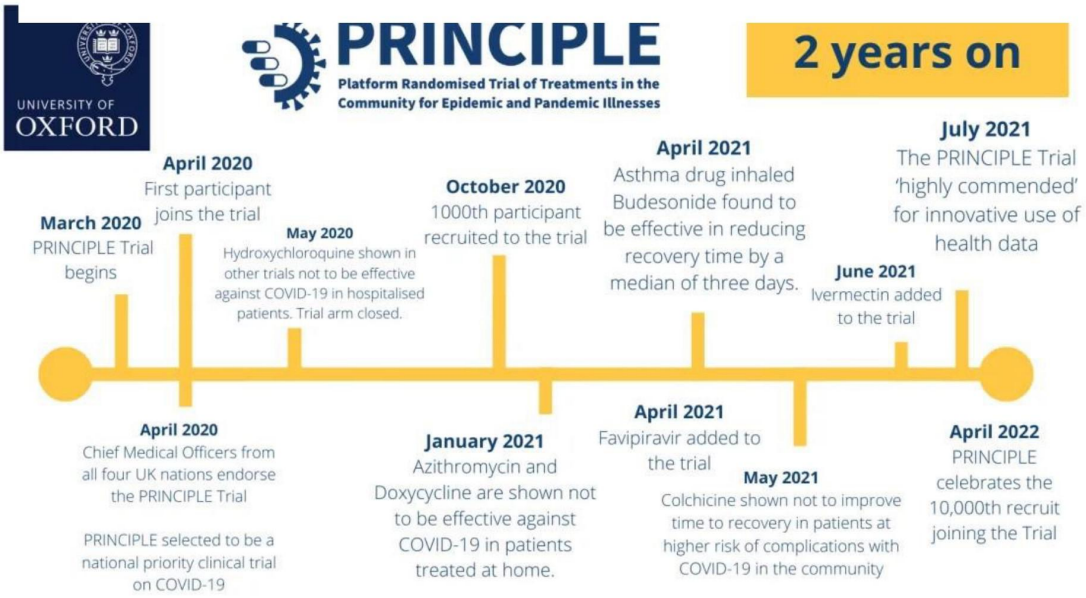


Figure 8

e. Patient Engagement

99. At no point during the pandemic have the CEV/CV or severely immune suppressed been asked their views formally by the government.

f. Issues Arising in Devolved Nations

100. CVF set up a focus group of their membership based in Scotland and the following is a summary of the evidence that they received from that cohort:

Summary of Scottish patient experiences with vaccines:

101. There has been evidence of both effective and ineffective service organisation in Scotland. This could be seen within the same health board, but at different times. The initial vaccine roll-out was relatively straightforward, in terms of delivery, to Scottish CV/CEV patients and their families. Communications to patients broke down somewhat during the booster phase, when patients and families were kept less informed by individual health boards about eligibility criteria and timescales for delivery. The eligibility criteria seemed to be particularly confused with regards to other family members of clinically vulnerable households. Family members were turned away from vaccination centres, being told they were not eligible, despite previous and continued eligibility. There were particular issues with access to vaccines for the children of CV/CEV patients,

with staff on booking phonelines unaware that such children were eligible, and the delivery of vaccines to children being restricted to only a few centres.

102. Due to lack of Covid-19 mitigations in Scottish hospitals, some patients were put off both reporting severe side effects and receiving further doses of vaccines. In the earlier stages of the roll-out, some patients found there was limited access to alternatives to mRNA vaccines, such as Novavax or potentially Valneva, despite vaccine approval and clinical indication. However, other patients have found accessing alternatives to the mRNA vaccines a relatively smooth process.

103. In general, at all stages during the pandemic, Scottish CV/CEV patients and their families have been required to put in effort and to self-advocate to ensure the correct vaccines were administered at the correct times. Sometimes this was not achieved, despite intense efforts.

Therapeutic mAbs

104. Access to appropriate Covid-19 targeted monoclonal antibody (mAb) therapies has not been straightforward for Scottish CV/CEV patients throughout the pandemic. A reactive rather than proactive approach has been taken, leaving many immunocompromised patients feeling they have been purposely "hung out to dry". Rapid out-patient access to mAbs for active Covid-19 infection has been patchy, with patients having to rely on the individual expertise and awareness of their consultants, rather than centralised policy and guidelines. Patients have been told that they may have access to mAbs if, and only if, they are admitted to hospital for severe Covid-19. Many patients are aware that mAbs are of most use when given early in the course of infection and are likely to be able to prevent them having to be admitted. This situation has placed enormous stress on families, at a time when decisions must be taken early to prevent life-threatening consequences.

Evusheld

105. Access through the Scottish NHS to Evusheld, the only prophylactic antibody available for use in the UK, has not been in place. It is not possible to access Evusheld privately in Scotland, causing patients to travel hundreds of miles to England at their own cost and risk, for infusions of the therapy. Many CV/CEV families in Scotland have experienced deep frustration at the slow pace of decision making around Evusheld.

Although new viral variants have currently out-paced some of the benefits of Evusheld, it has still been shown to provide substantial life-saving protection to patients who have no other options. Without any other form of protection, many of the most vulnerable to Covid-19 continue to shield. The mental and physical cost of long-term shielding for such patients, and their families, is devastating. Many are left feeling like a burden to their loved ones, that society has turned its back on them, and that the government has abandoned them to die.

Paxlovid

106. Patients in Scotland have been increasingly finding that Paxlovid access has been delayed past the critical point where it is of clinical use in controlling the infection. There is no way to access the treatment privately in Scotland. This situation once again leaves patients and their families having to battle for treatment at the worst possible time. It has been difficult for patients and their families to find out how to access antivirals and if they are suitable for use with the patient's condition and current medications. In one case, antibiotics were offered to a patient to prevent secondary bacterial infection, without antivirals being offered to treat the primary Covid-19 infection. Extended courses of Paxlovid are also infrequently trialled in Scotland, despite increasing numbers of studies supporting this off-label use for initial infection and the prevention and treatment of sequelae such as Long Covid. Many patients are applying to the Panoramic trial, simply in the hope of having a 1 in 2 chance of accessing Paxlovid.

g. Vaccination of Children

107. The rollout of Covid-19 vaccines to children in the UK has been a subject of considerable concern and debate. While the vaccination campaign for adults achieved significant success with the government proudly announcing milestones, the journey towards vaccinating children has been fraught with various challenges and delays. CVF aims to shed light on the intricacies and complications that emerged during the process, resulting in difficulties accessing vaccines for younger age groups.

108. It is CVF's experience that delays occurred due to multiple factors:

    a. Delayed approval by the Joint Committee on Vaccination and Immunisation ("JCVI") for children's vaccines compared to Europe and the USA.
    b. Inaccessibility of doses via the community pharmacy route for children.

c. *Pulse* (a news publication directed at GPs) reported that at least a quarter of English GPs opted out of vaccinations before the rollout to vulnerable high risk 12 to 15-year-olds **[Exhibit LWCF/35 – INQ000470347]**.
d. Variability in local availability of child vaccine doses.
e. The absence of walk-in options for younger clinically vulnerable children, requiring clinician identification and appointment allocation.
f. Children not being identified as eligible based upon third-party risk to an immune suppressed household member.
g. Processing of staff and volunteers by the Disclosure and Barring Service ("DBS").
h. The need for additional specialised training for vaccinators to ensure safe administration of vaccines to children.
i. Public Health England ("PHE") had to "Green light" vaccine centres before doses could be administered.

109. Families with clinically vulnerable members grew increasingly desperate to secure Covid-19 vaccines for their children as delays were considerable compared with other comparable nations. Some who had the financial means resorted to becoming health tourists, travelling to countries such as the USA or European countries in order to allow their children to return to school more safely.

110. The identification of children who were eligible for vaccination in priority groups was frequently challenging and many parents had to contact GPs and specialists repeatedly to ensure their children were correctly coded and on the list. However, it was even more complicated for children who qualified for early vaccines based on a third-party immunocompromised member of the household as the computer system did not appear to be set up to link medical data in this way. Unlike adults who could book their vaccinations conveniently via the National Booking Service ("NBS"), parents in clinically vulnerable families frequently encountered considerable difficulties in accessing appointments. Many issues, which had been identified earlier in the rollout, did not appear to improve significantly with subsequent age categories or even for repeat doses for the same children.

111. One notable aspect of the vaccination campaign for children was the prolonged wait for approvals. Unlike adult vaccines, where the JCVI proudly highlighted parallel processes implemented to accelerate approvals, children's approvals were seemingly not prioritised. Delays for each age category extended for lengthy periods, often over a year, in comparison to other similar countries. The uncertainty surrounding the approvals, and

at times, the rhetoric used in discussing children's vaccinations occasionally verged on antivax sentiments, which complicated the process further.

112. A particularly divisive issue was the discussion around vaccine safety for children. In a JCVI statement on Covid-19 vaccination of children aged 12 to 15 years **[Exhibit LWCF/36 – INQ000470348]**, the safety of children's vaccines was framed as a comparison between the risks of the vaccine from vaccination, rather than considering the outcomes from inevitable infection as expressed by the CMOs in a joint letter dated 13/09/2021 setting out their advice to ministers on offering the vaccine to 12 – 15 year olds in which they say: '*The Covid-19 Delta variant is highly infectious and very common, so the great majority of the unvaccinated will get Covid-19*' **[Exhibit LWCF/37 – INQ000066869]**. This is evidence of the proposition that children would inevitably be infected with Covid-19 and this should have been considered by the JCVI when deciding on whether the vaccine should be offered to 12 – 15 year olds. Long Covid was notably absent as a risk factor, as was the consideration of the vaccine's impact on transmission, which is one of the main reasons why healthy children are offered annual influenza vaccines. This approach sparked significant debate and contributed to a reduction in vaccine confidence and a reduced uptake **[Exhibit LWCF/38 – INQ000470350]** when compared to uptake of other paediatric vaccines prior to the pandemic according to the national Childhood Vaccination Coverage Statistics for England in 2022-23 **[Exhibit LWCF/39 – INQ000470351]** and **[Exhibit LWCF/40 – INQ000470352]**.

113. This has also led to a concerning rise in general antivaccine sentiment and a decline in uptake of other paediatric vaccines via the routine childhood immunisation schedule.

114. Independent SAGE members criticised JCVI vaccine approvals for 12 to 15-year-olds and 5 to 11-year-olds. They were "*slow, confused*" and "*lacked urgency*" **[Exhibit LWCF/41 – INQ000470353]**, CVF would agree with this assessment. Much was made in the media that the offer for the 5 to 11-year-olds was "*non-urgent*". Yet, New Zealand and the USA promoted vaccines for children as vital to keep children "*safe*" and "*protect*" communities **[Exhibit LWCF/42 – INQ000470354]** and **[Exhibit LWCF/43 – INQ000470355]**.

115. Whilst vaccination efforts were significantly impacted by disparities across various groups, due to widespread mistrust, which resulted in inequalities in vaccine uptake, CVF members were less affected, but some questions were raised in the group. It is important to note that CVF is a self-selecting group of proactive families, who then

become more informed by CVF. Therefore, in that respect only, the vast majority of CVF's membership cannot be seen to represent all vulnerable households. CVF would like further information regarding how vaccine uptake varied at different times within different clinically vulnerable sub-groups, such as household members of immune suppressed persons, children, older adults, clinically vulnerable.

116. The issue of testing positive for Covid-19 before vaccines were administered posed a significant challenge especially for children and young people in schools and colleges. In some instances, the resulting substantial delays, in combination with the lack of availability to certain groups at specific times, may have directly and indirectly reduced overall vaccine uptake. Priority groups were treated differently. Those in at-risk categories, such as children living with someone with a compromised immune system, were able to be vaccinated just 28 days following an infection. However, their healthy counterparts had to wait 12 weeks before they were eligible for vaccination. This raises serious concerns about decision-making and its potential to cause inequalities. Clinically vulnerable families often have healthy children, but they faced a higher risk of severe outcomes if the children contracted Covid-19 and transmitted it at home. In environments like schools with high infection rates, the risk of transmission to our families was significant. Infections risked lives and delayed the vaccination process further risking families. Infection in a family could delay vaccination for multiple members by 12 weeks, heightening risks to vulnerable people in the household. Children in clinically vulnerable families risked educational disruptions, either from prolonged school withdrawal until fully vaccinated or temporary absences during high case numbers, widening the gap in learning. Additionally, all of these factors added to the often intense social isolation and stress experienced by children and families.

117. There was a very small number of people within CVF who were influenced by misinformation and disinformation. One myth around "shedding" disseminated by antivaxxers misled some parents into believing their children may have some protection following the vaccination of an adult. However, once concerns were raised and discussed within the group or via direct messaging or over the phone with the founder, Lara Wong, misconceptions were usually rapidly unpicked and resolved. All of those who raised concerns about vaccines told CVF that they went on to get their children vaccinated.

118. There was a general trend for children's Covid-19 vaccines: as the age of the cohort decreased, the difficulties they faced accessing vaccines increased. Some similar issues were observed in healthy younger adult groups, but to a much lesser extent.

119. Since the 'Living with Covid' policy was introduced by the government (first published on 21 February 2022 and most recently updated on 6 May 2022) **[Exhibit LWCF/44 – INQ000470356]**, comparisons have been made between Covid-19 and influenza. However, since Autumn 2021, all children from age 2, up to and including children in school year 11 (aged up to 16), are now offered the opportunity to receive influenza vaccinations (primarily through the school vaccination program) **[Exhibit LWCF/45 – INQ000470357]**. The UK Health Security Agency's briefing for primary schools highlights reduction in community transmission as a key benefit. The full document is exhibited at **[Exhibit LWCF/46 – INQ000470358]** but particular attention is drawn to the following:

> "*The benefits include protection against flu for the children who receive the vaccine and reduced transmission of flu in the community. This is because children play a key role in the transmission of flu, including to those who may be at higher risk from the complications from flu such as the elderly*."

120. Children, including toddlers, who are "*close contacts of immunocompromised individuals*" are actively encouraged by healthcare professionals to take up influenza vaccines. Unlike influenza, Covid-19 vaccinations are now inaccessible to healthy children. This includes all children who, having turned 5 on or after 1 September 2022, have been deprived of any vaccine offer, despite the recognised consequential risks to their health. There is also a concern that healthy children, who may have acquired Gillick competence (i.e. they are mature enough to consent to treatment) or due to other reasons, including family members' health, are now denied the opportunity to complete their vaccine course. As things stand, these young people will never attain the same level of vaccination as healthy adults, who received an offer of 3 doses in response to the emergence of Omicron, leaving children without the same level of protection.

121. The following sections outline CVF's specific concerns, in relation to four different age groups: "16 to 17-year-olds", "12 to 15-year-olds", "5 to 11-year-olds" and "6 months to 4-year-olds".

(i) 16 to 17-year-olds

Priority Groups

122. 16 to 17-year-olds who were CEV, CV, or living in a household with a severely immunosuppressed person were offered vaccines with the adult cohorts (groups 4 & 6) **[Exhibit LWCF/47 – INQ000302492]**.

123. **National Booking Service**. As 16-year-olds are no longer paediatric patients within the NHS, these young people should have been able to access vaccination at a similar time to adults with equivalent conditions. However, the NBS was inaccessible to 16 and 17-year-olds, as they were only eligible for the Pfizer vaccine and there was no data on that service at the time (when all over 16-year-old CV and CEV cohorts became eligible) as to which vaccine would be available at any specified location on a particular day. The AstraZeneca vaccine had only been approved for those aged 18 years and older. Consequently, they had to rely on being contacted by their medical team and this added layer of administration which led to delays and often necessitated self-advocacy.

124. **Coding of patients**. CVF discovered that GPs had to code young people to allow them to access vaccines and young people who were able to get letters from their GPs saying they were coded found it considerably easier to access doses, because they were able to use them to confirm their eligibility at the vaccination centre.

125. **Second and subsequent doses**. Second doses, third primaries (where applicable) and subsequent boosters were all allocated via the adults' vaccination programme. This age group shared the same issues as the equivalent adults as described in paras 28 - 54 above.

Healthy individuals

126. Otherwise healthy young people living in households with non-severely immunosuppressed but clinically vulnerable members, including those with unvaccinated vulnerable people aged 0 to 15 years or adults who could not receive vaccines, faced a frustrating wait for the extension of general vaccine approval to their age category. This delay occurred despite the vaccine being deemed safe and effective for them by the MHRA **[Exhibit LWCF/48 – INQ000420516]** when the vaccine was first

approved in 2020 and being readily available in other countries, such as the USA **[Exhibit LWCF/49 – INQ000470361]**.

127. **Disclosure and Barring Service** ("DBS"). DBS checks were required for staff and volunteers working with children under 18 and involved in the vaccination process, unless supervised. This did slow down access for the healthy cohort. CVF is unsure as to why this issue was not previously resolved when young people had accessed doses alongside adults within the vulnerable cohorts.

128. **England and Wales**. GPs were told they could contact patients to invite them for appointments, unlike adults who could simply book their own. However, for CVF members, practically, this was not a simple process until the NBS opened up.

129. **Northern Ireland.** 16 to 17-year-olds were told that they could access vaccines via walk-in centres, this enabled a rapid and relatively hassle-free rollout to this group.

130. **Scotland.** Young people could register for doses online. CVF is not aware of any issues in Scotland for this cohort.

131. **National Booking Service**. Issues with the NBS were resolved for 16 to 17-year-olds on 24 September and this age group were finally able to book local vaccine appointments directly **[Exhibit LWCF/50 – INQ000470362]**. At the time, NHS England stated that "*The vaccination of 16-17 year olds is to be delivered primarily through Local Vaccination Services, but this service will be available in Vaccination Centres to increase cohort uptake*" **[Exhibit LWCF/51 – INQ000470363].**

132. **Single dose.** Only a single dose was offered to healthy 16 to 17-year-olds initially. The view of Professor Paul Hunter, who spoke to the APPG on Coronavirus on 10 August 2021 alongside JCVI chair Professor Andrew Pollard, was that "*one of the difficulties […] is actually how many of those younger people are already immune from 'natural infection'* ". 16 and 17-year-olds were included in the ONS antibody survey and he estimated that around 80-90% of 17-year-olds were likely to have been infected at that point in time. He further speculated that we did not know enough about potential side effects of vaccination in teenagers who were infected previously, but he felt we did know from "*other studies*" that the combination of one vaccine plus one infection triggered a "*robust immunity*" and hence they most likely would not need a second dose of vaccine.

133. However, CVF strongly suspected that those who had not been infected had a high probability of being from more cautious clinically vulnerable households and their needs were not being considered. Only 16 to 17-year-old household contacts of immunosuppressed people were at that point to receive two doses, if they themselves were healthy. This risked leaving vulnerable households more exposed because their children would have been the least protected whilst they remained amongst the most at risk.

134. NHS England announced that "*further guidance on the necessity of a second dose and the appropriate interval would be provided in due time.*" **[Exhibit LWCF/51 – INQ000470363]** Subsequently, a pattern emerged from the JCVI and / or the UK government which was characterised by an abundance of caution regarding offering all children's doses, which contrasted sharply with the previous enthusiastic rollout to adults.

135. **Second doses**. On 15 November 2021, as the Alpha wave was hitting, JCVI announced that healthy 16 to 17 year olds were finally being offered second doses, just as boosters were extended to healthy 40 year olds **[Exhibit LWCF/52 – INQ009470364]**. The announcement brought welcome relief to those with 16 to 17-year-olds in clinically vulnerable households, particularly where the young people had been attending schools and colleges in person during the second national lockdown, following the Prime Minister's announcement on 31 October 2020 that schools would remain open **[Exhibit LWCF/53 – INQ000470365]**.

136. It was announced that from 12 February 2023 in England that initial boosters for 16 – 49 year olds not in a clinical risk group would end, as shown in the JCVI update at figure 9 below:

Figure 9

137. **Boosters.** It was not until December 2021 that booster doses were recommended by the JCVI for healthy 16 to 17 year olds **[Exhibit LWCF/54 - INQ000147458].** The uptake of boosters was limited. CVF would be interested to see the breakdown of the distribution of doses between healthy and priority groups for all age categories.

138. The tables below summarises the uptake of each dose of the vaccine as taken from the ONS dataset [Full dataset can be found at [**Exhibit LWCF/55 – INQ000470367**] on vaccination rates among different age groups:

28/02/22[5]	First dose uptake (%)	Second dose uptake (%)	Third dose uptake (%)
16 to 17-year-olds	60.1	45.1	4.7

16/08/23[6]	First dose uptake (%)	Second dose uptake (%)	Third dose uptake (%)
16 to 17-year-olds	60.6	47.1	8.0

[5] This is the latest date that data was captured within the timeframe being considered by the Inquiry.
[6] This is the date that the most current data was captured that is outside the timeframe being considered by the Inquiry.

(ii) 12 to 15 year-olds

Priority groups

139. The rollout of vaccines to clinically vulnerable 12 to 15 year-olds faced a series of unique challenges, which caused considerable stress for children and adults in clinically vulnerable households. Whilst older high-risk children obtained doses alongside equivalent high-risk adults, the 12 to 15-year-old group found themselves seemingly prioritised behind healthy young adults. It is important to acknowledge that initially, the UK government allowed access to Covid-19 vaccinations for a very limited number of high-risk children under 16. The government's statement (see figure 10 below) noted: *"only those children at very high risk of exposure and serious outcomes, such as older children with severe neuro-disabilities that require residential care, should be offered vaccination"*. CVF do not have information on any of these children, or whether specific arrangements were made for them, however, we do believe that as it was not public knowledge, families may not have been informed of their child's eligibility. CVF would appreciate if the Inquiry obtained further information on the vaccine uptake in this group.

Children less than 16 years of age

Following infection, almost all children will have asymptomatic infection or mild disease. There is very limited data on vaccination in adolescents, with no data on vaccination in younger children, at this time. The committee advises that only those children at very high risk of exposure and serious outcomes, such as older children with severe neuro-disabilities that require residential care, should be offered vaccination with either the Pfizer-BioNTech or the AstraZeneca vaccine. Clinicians should discuss the risks and benefits of vaccination with a person with parental responsibility, who should be told about the paucity of safety data for the vaccine in children aged under 16 years. More detail on vaccination in children is set out in the Green Book – Immunisation Against Infectious Disease.

Figure 10

140. On 13 July 2021, we learned that only a tiny fraction of high-risk children were to be offered vaccines. Those with severe neuro-disabilities and other risk factors, severe learning disabilities, immunosuppression or children who were household contacts of an immunosuppressed person were approved to receive doses from 19 July, as vaccines were not yet recommended for others in the 12 to 15 year old age group, see figures 11

and 12 below. However, later in July 2021 it came to light that in an NHS England bulletin sent to GP practices it was suggested that primary care network groupings do not begin to vaccinate eligible 12 – 15 year olds until NHS England had confirmed details and revised the service specification as read in this article in The Pulse, 30 July 2021 **[Exhibit LWCF/56– INQ000470368]**:

> Children under 16 years of age, even if they are clinically extremely vulnerable, are at low risk of serious illness and death from COVID-19 and are not currently recommended for vaccination. However, as set out in chapter 14a of Public Health England's Green Book, vaccination may be appropriate for those 12-15 years of age with severe neuro-disabilities who tend to get recurrent respiratory tract infections. This would particularly apply to those who spend time in specialised residential care settings for children with complex needs.
>
> This option should be discussed between parents/guardians and the child's clinician or GP. For other children aged 15 and under, whilst further research is being completed, vaccination is not yet recommended.

Figure 11

Individuals aged 12 years or above at higher risk of severe COVID-19 infection.
This includes those with:

- severe neuro-disability and/or neuromuscular conditions that compromise respiratory function. This includes conditions (such as cerebral palsy, autism and muscular dystrophy) that may affect swallowing and protection of the upper airways, leading to aspiration, and reduce the ability to cough and resulting overall in increased susceptibility to respiratory infections
- children and young adults with learning disability (LD), including:
  - individuals with Down's syndrome
  - those who are on the learning disability register
  - those with profound and multiple learning disabilities (PMLD) or severe LD
- immunosuppression due to disease or treatment, including:
  - patients undergoing chemotherapy leading to immunosuppression, patients undergoing radical radiotherapy, solid organ transplant recipients, bone marrow or stem cell transplant recipients, HIV infection at all stages or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement disorder, SCID)
  - individuals who are receiving immunosuppressive or immunomodulating biological therapy including, but not limited to, anti-TNF, alemtuzumab, ofatumumab, rituximab, patients receiving protein kinase inhibitors or PARP inhibitors, and individuals treated with steroid sparing agents such as cyclophosphamide and mycophenolate mofetil
  - individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg per day (or for children under 20kg body weight a dose of 1mg/kg or more per day).
  - anyone with a history of haematological malignancy, including leukaemia, lymphoma, and myeloma and those with auto-immune diseases who may require long term immunosuppressive treatments

Individuals aged over 12 years who are contacts of immunosuppressed individuals

Those aged 12 years and above who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals **of any age** who are immunosuppressed (defined in table 3).

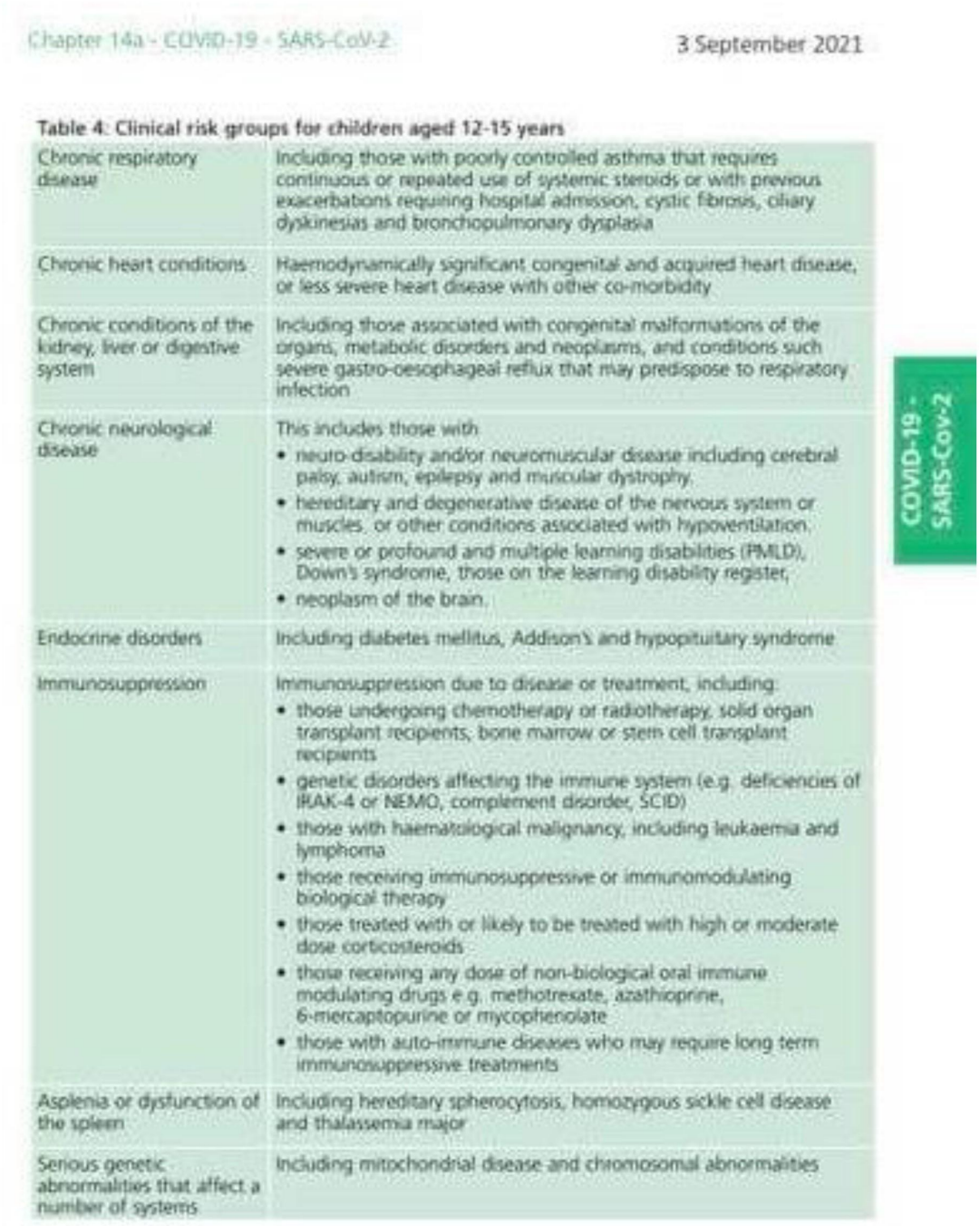
Age specific recommendations on vaccine type

Children under 16 and young adults aged 16-18 years

The Pfizer BioNTech vaccine has approval for use from 12 years old and currently has the most extensive safety data in those aged 12-15 years. This vaccine is therefore the preferred vaccine in this age group. Young people who have had a first dose of AstraZeneca vaccine, however, should complete with the same vaccine (see contraindications and precautions).

Figure 12, *Ch 14a. COVID-19 – SARS COV2 Green Book, as seen 13 July 2021 (document has since been updated)*

141. On 3 September 2021, a further group of clinically vulnerable 12 to 15 year olds were added to the Green Book, see figure 13 below.



Chapter 14a - COVID-19 - SARS-CoV-2 3 September 2021

Table 4: Clinical risk groups for children aged 12-15 years

Chronic respiratory disease	Including those with poorly controlled asthma that requires continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital admission, cystic fibrosis, ciliary dyskinesias and bronchopulmonary dysplasia
Chronic heart conditions	Haemodynamically significant congenital and acquired heart disease, or less severe heart disease with other co-morbidity
Chronic conditions of the kidney, liver or digestive system	Including those associated with congenital malformations of the organs, metabolic disorders and neoplasms, and conditions such severe gastro-oesophageal reflux that may predispose to respiratory infection
Chronic neurological disease	This includes those with • neuro-disability and/or neuromuscular disease including cerebral palsy, autism, epilepsy and muscular dystrophy. • hereditary and degenerative disease of the nervous system or muscles, or other conditions associated with hypoventilation. • severe or profound and multiple learning disabilities (PMLD), Down's syndrome, those on the learning disability register, • neoplasm of the brain.
Endocrine disorders	Including diabetes mellitus, Addison's and hypopituitary syndrome
Immunosuppression	Immunosuppression due to disease or treatment, including: • those undergoing chemotherapy or radiotherapy, solid organ transplant recipients, bone marrow or stem cell transplant recipients • genetic disorders affecting the immune system (e.g. deficiencies of IRAK-4 or NEMO, complement disorder, SCID) • those with haematological malignancy, including leukaemia and lymphoma • those receiving immunosuppressive or immunomodulating biological therapy • those treated with or likely to be treated with high or moderate dose corticosteroids • those receiving any dose of non-biological oral immune modulating drugs e.g. methotrexate, azathioprine, 6-mercaptopurine or mycophenolate • those with auto-immune diseases who may require long term immunosuppressive treatments
Asplenia or dysfunction of the spleen	Including hereditary spherocytosis, homozygous sickle cell disease and thalassemia major
Serious genetic abnormalities that affect a number of systems	Including mitochondrial disease and chromosomal abnormalities

COVID-19 - SARS-CoV-2

Figure 13 *Ch 14a. COVID-19 – SARS COV2 Green Book, as seen 3 September 2021 (document has since been updated)*

142. However, families discovered that not all of the conditions previously identified as CV or CEV for 16-year-olds were listed. Considerable stress and further advocacy was required of behalf of the children not listed, in the hopes of accessing vaccines.

Quote 32 from CVF Member

"I had to do a hell of a lot of jumping up and down; writing to my local MP, chasing our local healthcare trust, in order to make sure that my CEV child got the vaccine once it had been approved for over 12s. The process took forever, it was ridiculous. When we finally managed to get an appointment, we had to queue up with healthy 18 year olds who had been out all night clubbing! Hardly seemed appropriate that my CEV child who was on the shielding list, was put in the same category. The people at the vaccine centre were kind and caring, wore full PPE and allowed us to sit outside to wait afterwards because it was so busy inside."

Anon member

143. Highly vulnerable 12 to 15 year olds encountered a multitude of issues as they attempted to access Covid-19 vaccines across the UK. These challenges stemmed from various factors which impacted the timely and equitable distribution of vaccines to this age group. Many of the difficulties are listed below:

a. **Vaccine shortages.** It had previously been reported in *The Telegraph* that there was a shortage of Pfizer vaccine doses available for the healthy 18-year-old cohort, the same vaccines that were required for clinically vulnerable children **[Exhibit LWCF/57 – INQ000470369]**. The government was clearly under significant pressure to meet the targeted political 'roadmap' deadline of 19 July, to announce that all adults had been offered a first dose and two-thirds offered a second dose, it was a moment of high stress for our members when it became evident that far more vulnerable 12 to 15-year-olds had been deprioritised in the name of "Freedom Day". Dose procurement issues were finally resolved in September 2021, when the Department of Health and Social Care announced a large Pfizer order arrived to kick start the next adult vaccination campaign for "Autumn boosters" **[Exhibit LWCF/58 – INQ000470370]**. At this time the vulnerable children's group was also extended.

Quote 33 from CVF Member

"I had a massive battle to try and get my CV (clinically vulnerable) son his vaccine as he was 14, and the government prioritised healthy 18-year-olds over a vulnerable child. I wrote to everyone in authority I could think of and got nowhere. It was horrendous. That affected my mental health more than anything. The medical professionals couldn't quantify his risk but equally didn't want to stick their heads above the parapet and say he could get a vaccine.

I then had to fight for his brother who is a young carer to get one as well – his anxiety was through the roof at 15 at being forced back to an unsafe school environment and he was terrified of catching Covid and bringing it home to kill his mum and brother. The fight for paediatric vaccines was just an horrendous time. To know the government aren't interested in your vulnerable child was awful – but it was a portent of the future as now all CV/CEV are in that position." (May 2023)

Mary, aged 50

b. **Access and prioritisation.** Unlike other age categories, where an announcement of vaccines available to a new cohort led to vaccine access opening the following day, there was a significant lag between the fanfare of the public announcement and the reality of accessing doses. Frustration grew when healthy 16 to 17 year-olds, who had been announced at the same time, were vaccinated both more easily and rapidly than the much higher-risk 12 to 15 year-old vulnerable group.

c. **Green Lighting of Vaccination Centres.** Another cause of delays was the failure to 'Green Light' vaccination centres in advance of vaccine approvals to enable them to administer doses to children. We are aware there were various aspects to the process including:

(i) DBS checks of both staff and volunteers working with children and involved in the vaccination process.

(ii) Further specialist training was also required for the vaccinators to safely administer vaccines to children so they could be granted an essential 'paediatric certificate' **[Exhibit LWCF/51 – INQ000470363]**. The following training was required:

- "Safeguarding"
- "Basic Life Support"
- "Capacity and consent for children"

- "Handling difficult conversations" "risk/benefit conversations and handling delicate situations (e.g. in situations where the child is accompanied by a parent and needs to answer the question around pregnancy)."
- "IM injection administration: vaccinating into less developed deltoid muscles and managing a restless individual. "
- "Responding to psychogenic reactions to needles"
- "Working with children:"
- "Working with children with special educational needs and disabilities."

d. **General Practice Opt-Out.** One notable issue was the decision to allow GPs to opt out of participating in the second phase of the vaccine rollout, as reported by *Pulse* **[Exhibit LWCF/59 – INQ000470371]**. Primary Care Networks were then offered the opportunity to opt out of vaccinating 12 to 15 year old children **[Exhibit LWCF/60 – INQ000470372]**. They were told to identify and "*share a list of eligible patients with their local commissioner so they can arrange for these patients to be offered an appointment at another provider (e.g., another PCN-led vaccination site or Hospital Hub) by 27 September. This request is necessary for the reasons of public interest. CCGs should ensure eligible patients are invited for an appointment by 30 September*.". However, in many cases this appeared to not happen as suggested. Opt-outs had a direct impact on the accessibility of vaccines for high-risk adolescents in the 12-15 age bracket. Consequently, families often reported struggling to obtain vaccine doses if their own GP practices were not able to directly assist them.

e. **No Access via Walk-In Centres and Pharmacies.** Accessing vaccines through walk-in centres and community pharmacies was not a pathway available to age 12-15 clinically vulnerable children.

f. **National Booking Service.** The NBS, both online and phonelines, was also unable to assist CVF members. Parents were sent on an endless loop whereby they would contact either their GP or the NBS only to be deferred to the other. CVF believes that this caused inequalities as parents often needed to be tenacious, educated and well informed to be successful. These children had a more complex process of identification than preceding groups, involving identification by clinicians and booking of appointments at approved locations – CVF members frequently reported that their GPs were unable to help them.

g. **Clinically Extremely Vulnerable children.** On 23 August 2021, just before the return to school, parents and carers of children who were CEV were sent a letter to inform them that studies indicated they were at very low risk of severe illness from Covid-19, a copy of which is shown in a series of screen shots taken by a member of CVF **[Exhibit LWCF/61 – INQ000420520]**. As a result, CEV classification was revoked, and an end to formal shielding measures was recommended, even for children with exceptionally high risk, despite these children having received one dose of vaccine at best. Many parents were incredibly concerned that the studies may have been flawed as most CEV children had been heavily shielded since early 2020 and data was therefore both limited and biased.

h. **School Reopening Autumn 2021.** Children who qualified for vaccines were under pressure due to the imminent reopening of schools without mitigations. Parents and carers in clinically vulnerable families were acutely aware that it took 2-3 weeks for an immune response to develop following the first vaccine dose and this gave rise to additional stress as at this point most children across the UK were unprotected. The only exception was in Scotland, where schools reopened earlier than the other home nations, as NHS Scotland was able to initiate their rollout ahead of the rest of the UK. The Scottish Government announced vaccines would be available to vulnerable children much sooner, on 19 July 2021 **[Exhibit LWCF/62 – INQ000420521]**. Consequently, none of the children in this age group were fully vaccinated when the 2021 school year began and most were completely unprotected.

i. **Lack of Herd Immunity.** The absence of vaccine acquired immunity within the school population created a challenging situation for children in clinically vulnerable households. As schools reopened in Autumn 2021, post 'Freedom Day' and without mitigations, infections rapidly began to spread. Many parents, once again, felt compelled to make difficult decisions between the human rights to life and rights to education, as reported in *i News* **[Exhibit LWCF/63 – INQ000420522]**. Sending their unvaccinated or partially vaccinated children to school, into an unvaccinated population, put their children in a much higher risk situation for infections especially compared to adults who were mostly double vaccinated at that time.

j. **Vaccine tourism and Inequalities.** Unlike adult vaccines which were available locally, CVF members found they had to travel much further on average to attend appointments for their children aged 15 and under. In addition, the protracted approvals process by the JCVI, coupled with the lack of availability of vaccines

meant that some CVF members made the difficult decision to travel long distances to obtain this protection for their children sooner. Some travelled to other UK nations where they were approved sooner or may have been easier to access. A small number, who had the financial ability to and out of desperation, felt compelled to take additional risks by travelling further to European countries or North America. This created another inequality for those who had to wait for appointments sometimes struggled to travel long distances within their own county if their local GP had opted out of administering vaccines.

k. **Antivax protests.** As the antivax movement in the UK became more active, some high-risk families found themselves the target of abuse and anger when they finally were able to access hard fought appointments for protective doses.

Quote 34 from CVF Member

"I remember them trying to accost us on the way in and using abusive language towards us. We both definitely felt threatened by them, that's for sure. They'd stationed themselves right at the entrance to the building and it was specifically an entrance only really being used by folk coming to the vaccination centre so you couldn't really avoid them. My son was 12 then, but there was another mother who came in with 2 young children. She had felt really threatened by them too.

The staff simply called the police when we made them aware, which was fine as they quickly responded thank goodness. We were lucky in that the police had come and moved them on by the time we left as I didn't want to have to run the gauntlet on the way out."

Christina, aged 49 and John, aged 12

Healthy individuals

144. The decision-making process regarding Covid-19 vaccination for healthy 12 to 15-year-olds raised concerns and appeared to result in a much lower vaccine uptake in this age group. CVF acknowledges that, in medical practice, all drugs, vaccines, and procedures carry inherent risks and benefits. However, if the risks of a drug or vaccine exceed its benefits, it should not be authorised by the MHRA. As Covid-19 is both highly infectious and prevalent and as we have seen in a joint letter by the CMOs, infection was inevitable **[Exhibit LWCF/37 – INQ000066869]**. The risk of severe illness, hospitalisation, or death due to Covid-19 may be lower amongst those aged 12-15, but it is not non-existent and

does pose a risk for clinically vulnerable children who live alongside healthy siblings, friends and classmates.

145. CVF believes that the view of the JCVI on 4 August 2021 **[Exhibit LWCF/64 – INQ000420524]** and again on the 13 September 2021 **[Exhibit LWCF/65 – INQ000420525]**, regarding the vaccination of 12 to 15-year-olds was too conservative, as it considered the advantages of vaccination to be insufficient to justify a universal offer to this age group. The wider public health benefits and the risks of universal vaccination appear to have not been adequately considered by the JCVI. Particularly as many children in clinically vulnerable families found themselves locked out of education or missing significant amounts of schooling due to the risks posed by perpetually high transmission in schools. Data collected by an attendance survey conducted by CVF via their Facebook group, shown in figures 14 and 15 below, from CVF indicates an incredibly high rate of school absences for children in clinically vulnerable households even when compared to other groups previously known to experience high persistent and severe absences. CVF would like to know why this, likely known, impact was not considered by decision-makers.

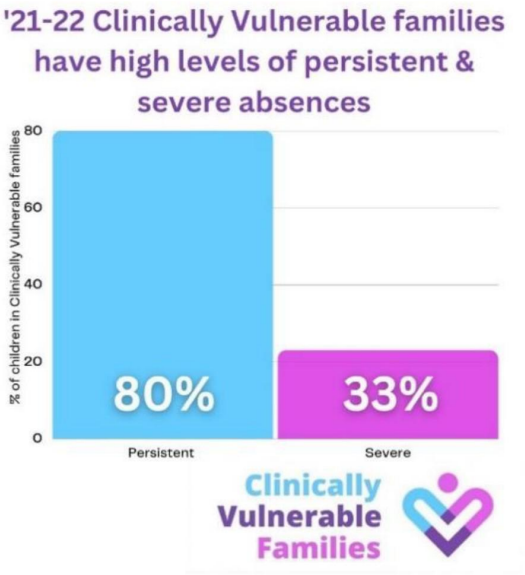


Figure 14

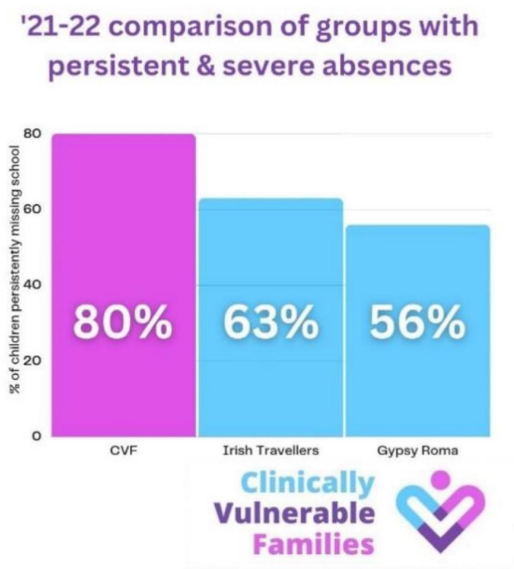


Figure 15

146. It was notable that the Chief Medical Officers ("CMOs") had to take exceptional action to overrule the normal decision-making process of the JCVI. CVF strongly supports the CMOs view that education plays a critical role in children's well-being and believes that the disruptions caused by the pandemic has taken a disproportionate toll on their

families. The effects of disrupted education and uncertainty on mental health are well-recognised, and there is concern that extended disruption to education can have lifelong effects on health and reduced life chances.

147. CVF believes that vaccinations are important from a public health perspective to reduce the prevalence and evolution of Covid-19 variants, also to minimise school disruption experienced by all children. Regular outbreaks of infections are seen in schools, as children are widely recognised to drive transmission of respiratory infections including Covid-19 and influenza. The CMOs did not appear to consider how vaccination can reduce transmission and the protection offered to the wider community. For this reason alone, the NHS offer children regular seasonal influenza vaccines, not only to reduce educational disruption, but to protect communities.

148. The JCVI / CMOs decision also failed to take into account the risks of sequalae (the after effects of a disease) as their focus was childhood mortality. Other comparable countries, such as the USA, have now integrated vaccines into their paediatric schedule **[Exhibit LWCF/66 – INQ000420526]**.

149. **School-based Covid-19 Vaccination Programme.** A school-based Covid-19 vaccination programme was set up across the UK, with some national differences.

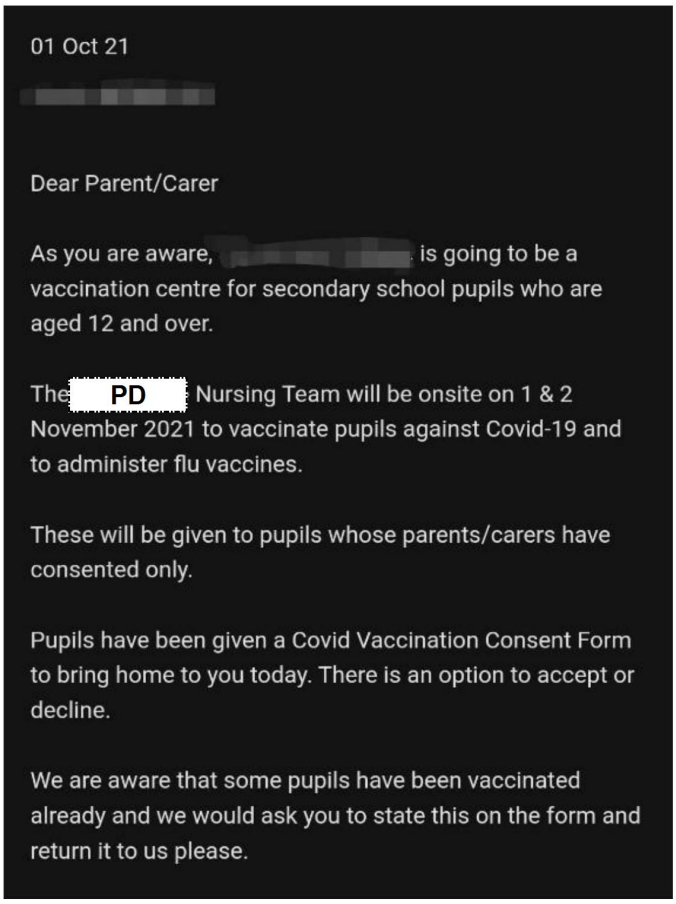
150. The Year 7 group, aged 11 to 12 years, was not included in the school-based vaccination program which was implemented across the UK. CVF believe that this exclusion stemmed from practical considerations, such as the ability to easily identify those who were aged over 12 at the point of vaccination, that could have been addressed. In other age categories, older individuals were offered doses for young people three months prior to their qualifying birthday. If a similar and equitable policy had been implemented, in conjunction with the delays in the rollout, a significant portion, possibly between a third to half, of Year 7 children could have been vaccinated.

151. **Consent.** The concept of Gillick-competency was given significant media attention, despite it being a well-established protocol. According to NHS guidance, "*If children over 16 or a child deemed Gillick-competent consent to treatment, parental consent cannot override their decision*" **[Exhibit LWCF/51 – INQ000470363]**. However, it rapidly became controversial in schools, which were serving as vaccination centres and became focal points for anti-vax protesters. A *Guardian* article reported that "*close to 80% of schools had been targeted by anti-vaxxers*", **[Exhibit LWCF/67 –**

INQ000420527] this created an atmosphere of tension and concern for school communities. Teachers and Head teachers were frequently targeted including threats of "*legal action and told they could face fines of up to £20 million or "life imprisonment"*" **[Exhibit LWCF/68 – INQ000420528 and Exhibit LWCF/69 – INQ000420529].** Children in clinically vulnerable families were frequently the only ones wearing masks at school, and parents were concerned about their children being targeted. When CVF members received antivax leaflets they were generally 'carefully filed' in the bin. However, some documentation misrepresented itself as from the NHS and this may have fooled some in clinically vulnerable households, as even headteachers were occasionally confused into passing them on to parents as genuine communications **[Exhibit LWCF/70 - INQ000420530]**.

152. CVF believes that the debate around Gillick-competency in the context of Covid-19 vaccinations for children in UK schools arose due to people questioning the legal right of children to be vaccinated without parental consent. Gillick competency, a principle established in 1985, assesses whether a child under 16 is mature enough to make their own decisions regarding medical treatment. The concept became relevant when Covid-19 vaccines were offered to 12 to 15-year-olds and schools faced parental opposition against children's consent. Guidance **[Exhibit LWCF/71 – INQ000420531]** clarified that while schools provide premises for vaccinations and distribute consent forms, the assessment of a child's Gillick competency is handled by healthcare professionals, not schools.

153. In response to the complexities of the Gillick-competency debate and threats of legal action against school staff, some schools sent out consent forms, as seen in figures 16 and 17 below provided by a member of CVF, and reassurances for parents and carers to accept or decline a Covid-19 vaccination for their child. They often sent further reassurances to parents e.g. "*These will be given to pupils whose parents/carers have consented only*".



01 Oct 21

[redacted]

Dear Parent/Carer

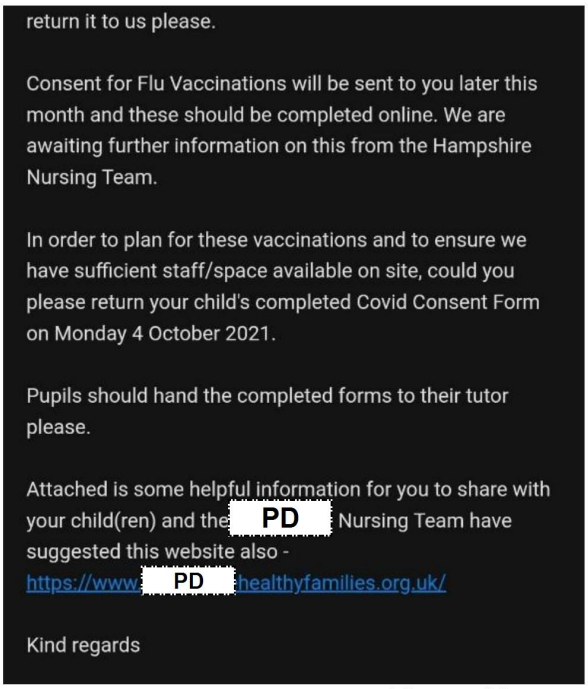
As you are aware, [redacted] is going to be a vaccination centre for secondary school pupils who are aged 12 and over.

The PD Nursing Team will be onsite on 1 & 2 November 2021 to vaccinate pupils against Covid-19 and to administer flu vaccines.

These will be given to pupils whose parents/carers have consented only.

Pupils have been given a Covid Vaccination Consent Form to bring home to you today. There is an option to accept or decline.

We are aware that some pupils have been vaccinated already and we would ask you to state this on the form and return it to us please.



return it to us please.

Consent for Flu Vaccinations will be sent to you later this month and these should be completed online. We are awaiting further information on this from the Hampshire Nursing Team.

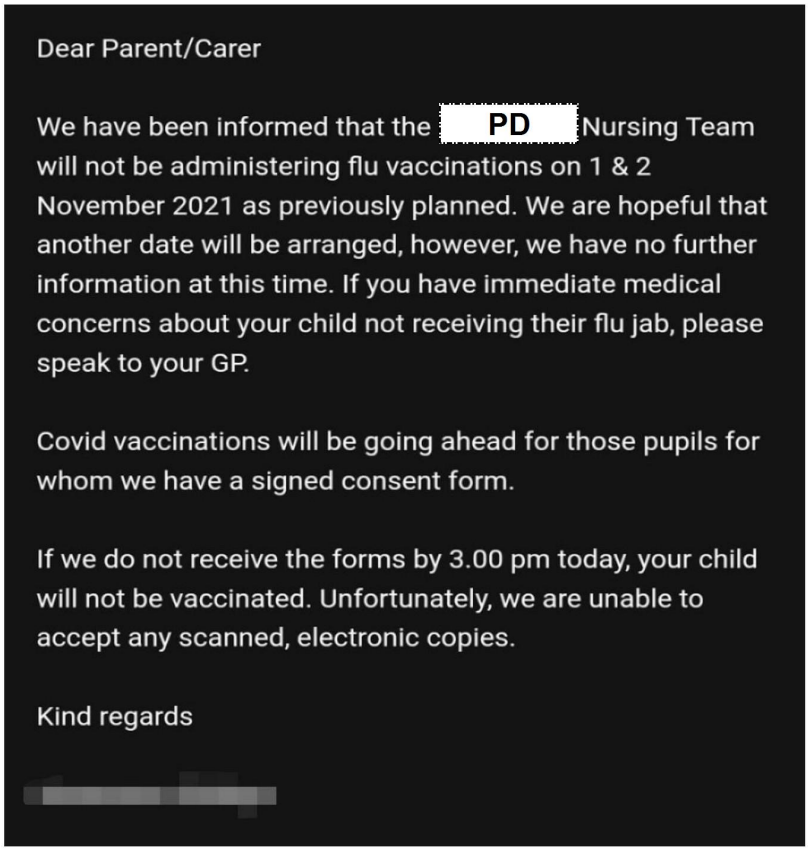
In order to plan for these vaccinations and to ensure we have sufficient staff/space available on site, could you please return your child's completed Covid Consent Form on Monday 4 October 2021.

Pupils should hand the completed forms to their tutor please.

Attached is some helpful information for you to share with your child(ren) and the PD Nursing Team have suggested this website also - https://www.PD healthyfamilies.org.uk/

Kind regards

Figure 16



Dear Parent/Carer

We have been informed that the PD Nursing Team will not be administering flu vaccinations on 1 & 2 November 2021 as previously planned. We are hopeful that another date will be arranged, however, we have no further information at this time. If you have immediate medical concerns about your child not receiving their flu jab, please speak to your GP.

Covid vaccinations will be going ahead for those pupils for whom we have a signed consent form.

If we do not receive the forms by 3.00 pm today, your child will not be vaccinated. Unfortunately, we are unable to accept any scanned, electronic copies.

Kind regards

[redacted]

Figure 17

154. However, the distribution of these forms raises a critical issue: Did schools, or the NHS, allow parents or carers to override the rights of Gillick-competent children? This is further discussed in *Consent for covid-19 vaccination in children, BJM Journal 23rd September 2021 by Azeem Majeed et al* **[Exhibit LWCF/72 – INQ000420532]**.

England

155. On 20 September 2021 the NHS proudly announced, *"Jabs will start in hundreds of schools across the country this week with the NHS vaccination programme rolling out to others in the coming weeks."* **[Exhibit LWCF/73 – INQ000420533]** In practice, CVF members encountered significant challenges with the rollout, including slow progress and logistical issues. These difficulties led to delays in vaccine distribution, resulting in some children being overlooked for various reasons, including prior infection. Sometimes schools had to rearrange vaccination dates or arrange further appointments when vaccine stocks ran out or processing took a long time. Vulnerable families with children not in school but registered felt they had to take a risk to send their children in for vaccination as no alternative was readily available to them.

156. A reference to a plan *"to increase cohort uptake"* next to the 16 to 17 year old cohort is notably absent from the key considerations on the overview of 'design principles' for the 12 to 15 year-olds page 4 of **[Exhibit LWCF/51 – INQ000470363]**.

157. Other children who were registered as home-educated were eventually able to access vaccines through online bookings. However, CVF members who were not registered did not receive priority through this alternative vaccine delivery pathway and were generally vaccinated through schools.

Northern Ireland

158. The vaccination program in Northern Ireland, was similar to England, and primarily school-based, with GPs providing support where necessary. *"Most school-aged children aged 12 to 15 are expected to will primarily receive their COVID-19 vaccination in their school with alternative provision for those who are home schooled or in secure services."* **[Exhibit LWCF/74 – INQ000420534]**. CVF members reported access issues similar to those in England in Northern Ireland.

Scotland

159. In Scotland, the Covid-19 vaccination program for children and young people aged 12 to 15 years had an emphasis on accessibility and flexibility. The Scottish Government made these clear when then announced the program,

> *"This group will be offered their injections in drop-in clinics and community settings followed by each young person receiving a letter inviting them to attend a community clinic. For some rural Health Boards, those aged 12 to 15 will first be offered the vaccine at school. Following the initial phase, vaccines will be offered in both communities and schools so that anyone who hasn't been vaccinated but would like to be has the opportunity to take up the offer."*
>
> **[Exhibit LWCF/75 – INQ000420535]**

160. Provisions were made for vaccination in more rural areas through school vaccination programs, as opposed to community settings. Parents and carers with concerns about the vaccines were encouraged to visit drop-in clinics for advice from a vaccinator. **[Exhibit LWCF/76 – INQ000420536]**

161. Unlike England, where vaccinations were mainly administered in schools with a later option added for online bookings, Scotland offered a combination of scheduled appointments and drop-in clinics. This approach provided a more adaptable framework which was especially beneficial to our families who often needed more flexible scheduling options. The Scottish Government's strategy ensured that all eligible individuals in this age group had access to the vaccine, regardless of their schooling or health status. CVF are not aware of any specific issues in Scotland.

Wales

162. The vaccination program for 12 to 15 year-olds in Wales differed considerably from that in England, in terms of its delivery. Rollout involved inviting children directly by letter, with the majority of vaccines being administered at mass vaccination centres. In some areas vaccination was also carried out in schools. Welsh Health Minister, Eluned Morgan MS, stated that the vaccine would be offered to all children in this age group by the end of the October half-term **[Exhibit LWCF/77 – INQ000420537]**. She also explained the reasoning behind their approach in her written cabinet statement *"a blended model of offering the vaccine with all health boards primarily inviting this age*

*group to vaccination centres with some areas going through schools. The strength of this model is that it is based on local knowledge".***[Exhibit LWCF/78 – INQ000048770]** CVF received positive reports from members in Wales who accessed doses swiftly through this model, we even heard of one child who had secured two vaccinations before many members in England had received their first doses. The system in Wales particularly impressed CVF, as it had also identified the specific challenges faced by healthy children in severely immunosuppressed households and provided an online form for self-referral. **[Exhibit LWCF/79 – INQ000420539]**.

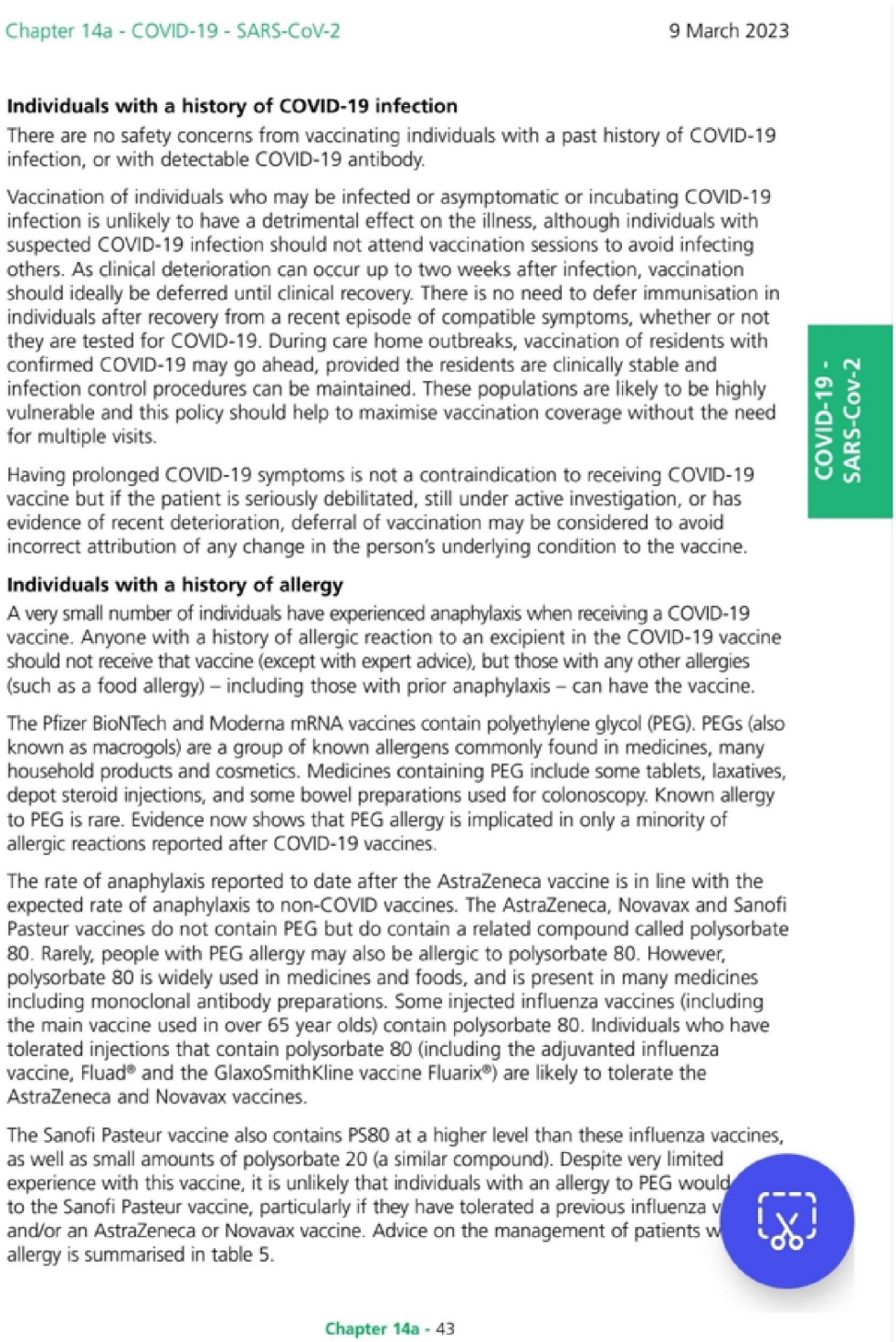
163. **Single dose.** Initially, the plan was to administer only one dose to this group, aligning with the decision made for healthy 16 to 17-year-olds, who were offered a single dose of the Pfizer vaccine. Members of CVF once again expressed their concern about the oversight of their children and families in this decision, both in terms of the direct and indirect consequences.**[Exhibit LWCF/80 – INQ000420540]**

164. **Second doses.** On 20 December 2021, it was announced that 12 to 15-year-olds could book via the NBS "as *schools break up for Christmas*", however, they would only be eligible for doses 12 weeks following their first doses. The protracted schools vaccination programme had been fraught with challenges and some children had been unable to access doses due to prior infections precluding them from accessing first doses for 12 weeks during the schools rollout, as it was apparently the plan to use infection as a part of the process to acquire immunity in this cohort to create a so-called 'hybrid immunity'. Consequently, some of the children booking doses in December were booking their first doses. The constant infections combined with the 12 week rule precluded many children from acquiring first or second doses in this cohort. Even clinically vulnerable families found this challenging.

165. In the US there was a 3 week gap between vaccines and 'hybrid immunity' did not appear to feature as a part of their immunisation plan **[Exhibit LWCF/81 – INQ000420541]**. They subsequently changed their recommended gap between doses to extend it to 8 weeks **[Exhibit LWCF/82 – INQ000420542]**. In the UK it should be noted that children who were household contacts of an immunosuppressed person were also recommended an 8 week gap.

> "COVID-19: the green book, chapter 14a", as shown in figure 18 below, states there is no safety concerns even for people who are currently infected with Covid-19. "*There is no need to defer immunisation in individuals after recovery*

from a recent episode [..]". CVF is concerned about the apparent utilisation of infections to promote this allegedly "robust" immunity in the previously naïve young population.



Chapter 14a - COVID-19 - SARS-CoV-2 9 March 2023

Individuals with a history of COVID-19 infection

There are no safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody.

Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, although individuals with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others. As clinical deterioration can occur up to two weeks after infection, vaccination should ideally be deferred until clinical recovery. There is no need to defer immunisation in individuals after recovery from a recent episode of compatible symptoms, whether or not they are tested for COVID-19. During care home outbreaks, vaccination of residents with confirmed COVID-19 may go ahead, provided the residents are clinically stable and infection control procedures can be maintained. These populations are likely to be highly vulnerable and this policy should help to maximise vaccination coverage without the need for multiple visits.

Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

COVID-19 - SARS-Cov-2

Individuals with a history of allergy

A very small number of individuals have experienced anaphylaxis when receiving a COVID-19 vaccine. Anyone with a history of allergic reaction to an excipient in the COVID-19 vaccine should not receive that vaccine (except with expert advice), but those with any other allergies (such as a food allergy) – including those with prior anaphylaxis – can have the vaccine.

The Pfizer BioNTech and Moderna mRNA vaccines contain polyethylene glycol (PEG). PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare. Evidence now shows that PEG allergy is implicated in only a minority of allergic reactions reported after COVID-19 vaccines.

The rate of anaphylaxis reported to date after the AstraZeneca vaccine is in line with the expected rate of anaphylaxis to non-COVID vaccines. The AstraZeneca, Novavax and Sanofi Pasteur vaccines do not contain PEG but do contain a related compound called polysorbate 80. Rarely, people with PEG allergy may also be allergic to polysorbate 80. However, polysorbate 80 is widely used in medicines and foods, and is present in many medicines including monoclonal antibody preparations. Some injected influenza vaccines (including the main vaccine used in over 65 year olds) contain polysorbate 80. Individuals who have tolerated injections that contain polysorbate 80 (including the adjuvanted influenza vaccine, Fluad® and the GlaxoSmithKline vaccine Fluarix®) are likely to tolerate the AstraZeneca and Novavax vaccines.

The Sanofi Pasteur vaccine also contains PS80 at a higher level than these influenza vaccines, as well as small amounts of polysorbate 20 (a similar compound). Despite very limited experience with this vaccine, it is unlikely that individuals with an allergy to PEG would to the Sanofi Pasteur vaccine, particularly if they have tolerated a previous influenza v and/or an AstraZeneca or Novavax vaccine. Advice on the management of patients w allergy is summarised in table 5.

Chapter 14a - 43

Figure 18 - Ch 14a. COVID-19 – SARS COV2 Green Book, p43, 9 March 23

Boosters. Healthy 12 to 15 year olds not residing in households with non-severely immunosuppressed individuals were only ever able to access a maximum of two doses and never provided with 'Booster' vaccines which were offered to all older age groups. This decision was made despite substantial evidence indicating that booster vaccines significantly increased protection against severe disease and death. Lower infection rates and transmission rates, **[Exhibit LWCF/83 – INQ000420543]** thereby offering potential benefits in reducing risks for young people. By extension the risks to clinically vulnerable families with young people, exposed to high levels of transmission in schools without other mitigations, are also reduced.

166. The below summarise the uptake of each dose of the vaccine [Full dataset can be found at **Exhibit CF/55**] as taken from the ONS dataset on vaccination rates among different age groups:

28/02/22[7]	First dose uptake (%)	Second dose uptake (%)	Third dose* uptake (%) *available to Priority groups only
12 to 15-year-olds	40.5	26.8	0.5

16/08/23[8]	First dose uptake (%)	Second dose uptake (%)	Third dose* uptake (%) *available to Priority groups only
12 to 15-year-olds	42.0	31.7	1.2

(iii) 5 to 11-year-olds

Priority groups

167. By the time the announcement was made on 24 December 2021 that vulnerable children aged 5 to 11 years were to receive Covid-19 vaccines **[Exhibit LWCF/84 – INQ000420544]** the rest of the UK had long since moved on **[Exhibit LWCF/54 – INQ000147458]**. Indeed, by 15 December 2021, all healthy people over the age of 18 in the UK could book their third vaccine doses. However, the situation faced by the most

[7] This is the latest date that data was captured within the timeframe being considered by the Inquiry.
[8] This is the date that the most current data was captured that is outside the timeframe being considered by the Inquiry.

vulnerable 5 to 11-year-old children was starkly different. Despite concerned parents reaching out to their GPs with the hope of securing a pre-Christmas vaccine, this did not happen. Families found themselves repeatedly in touch with GPs, the 119 service, CCGs and consultants, desperately seeking answers and help. Yet, it was not until over a month later that the first doses became available for these vulnerable children.

168. **Lower Dose.** The younger children were given a smaller 10 microgram (µg) dose, compared to the 30 µg dose used for those aged 12 and over. **[Exhibit LWCF/85 – INQ000420545]** The procurement and distribution of these new vials caused a delay, which resulted in inequalities as some areas received the vaccines before others. In a tweet (figure 19 below) dated 17 January 2022, a GP on Twitter (X) identified three reasons for the delays stating

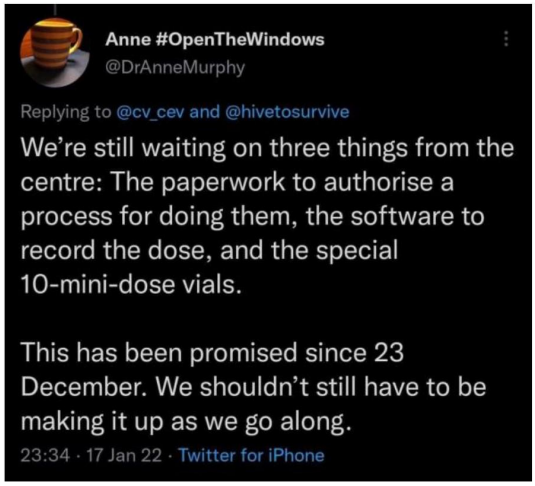


Figure 19

169. Sajid Javid MP made a statement to explain that vials arrived mid-January and vaccination was planned to start at the end of January **[Exhibit LWCF/86 – INQ000420546]**. Some CVF members were able to access titrated adult doses much sooner, however, these were given as a rare exception because most clinics were not always willing or able to offer this alternative. CVF had reports of fractional doses being offered in Scotland, Wales and Kent and Harringay.

170. In response to emails from CVF members to local vaccination teams, one member received an email, as seen in figure 20 below, which identified possible 'exceptional clinical circumstances' in which children could be vaccinated with a fractional dose of

"adult Pfizer", although this would be off-label and at the discretion of the clinical lead at the vaccination site. These included imminent therapy or treatment that would impair subsequent vaccine response and heightened clinical concern regarding the threat of Covid-19 to the child or an immunosuppressed family member. CVF members were keen to access fractional doses as the Green Book (dated 24 December 2021) indicated that they could *"be considered on a case by case basis"*, as seen in figure 21 below, however, they reported that vaccination centres frequently could not, or would not, offer them regardless of risks or circumstances.

Thank you for your email.

The JCVI have made recommendations to vaccinate at risk 5-11 yr. olds and household contacts of the immunosuppressed in this age group, however it has **not** been operationalised yet by the NHS.
We are currently awaiting paediatric doses of Pfizer which are not yet available. The anticipated start date is likely to be towards the end of January.

Once the NHS are ready to receive 5-11 year olds classed as CEV, then the Information will be shown on the NHS website and the Sussex Health & Care website (see links below) –

https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/book-coronavirus-vaccination/

https://www.sussexhealthandcare.uk/keepsussexsafe/covid-19-vaccinations/where-can-i-get-my-covid-19-vaccination/walk-in-vaccination-sessions/

Individuals where there is **exceptional clinical circumstances** can be vaccinated using a fractional dose of adult Pfizer (noting this would be off label and at the discretion of the clinical lead at the vaccination site). Examples of clinical exceptionality would be -

- Imminent therapy or treatment that would impair subsequent vaccine response
- Heightened clinical concern regarding the threat of COVID to the child or an immunosuppressed family member

There is guidance from the government, here: https://www.gov.uk/government/publications/covid-19-vaccination-resources-for-children-aged-5-to-11-years/a-guide-for-parents-of-children-aged-5-to-11-years-of-age-at-high-risk which states: ***Your GP (family doctor) or specialist should advise you about the COVID-19 vaccinations for your child. Some parents may receive a letter, or a phone call to invite them for to make an appointment for their child to be vaccinated.***

Figure 20

Pfizer BioNTech COVID-19 BNT162b2 vaccine (tozinameran)/Comirnaty®)

For those aged 12 years and above, the dose of Pfizer BioNTech COVID-19 vaccine is 30μg contained in 0.3ml of the diluted vaccine. After dilution each multidose vial can be used to deliver six doses of 0.3ml.

For children aged 5-11 years, the dose of Pfizer BioNTech COVID-19 vaccine is 10μg. The paediatric formulation Comirnaty®10μg is supplied in a multidose vial, with each vial containing 10 doses of 0.2 mL (after dilution with 1.3ml of saline). The paediatric formulation should be used, although 10μg (0.1ml) of the diluted adult/adolescent vaccine may be an alternative when protection is required rapidly and the paediatric formulation is not available. The use of a fractional adult/adolescent vaccine would be off-label and can be considered on a case by case basis.

The primary course should be administered in two doses, a minimum of 21 days apart.

AstraZeneca COVID-19 vaccine (Vaxzevria®)

The dose of AstraZeneca COVID-19 vaccine is 0.5ml.

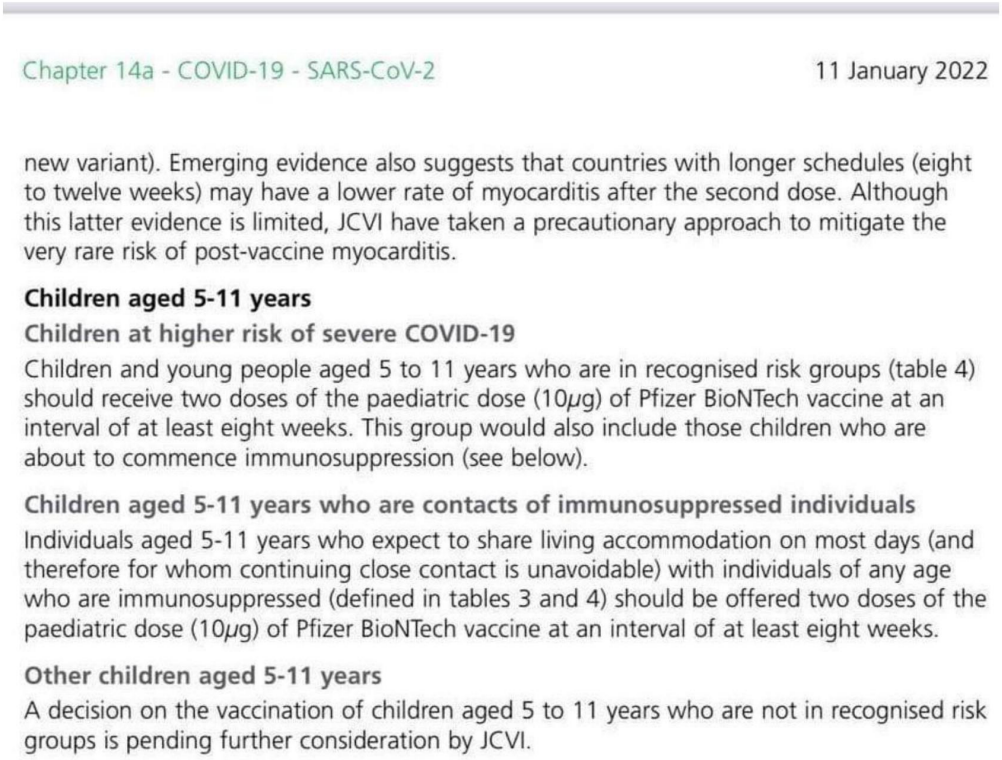
The primary course should be administered in two doses, a minimum of 4 weeks apart.

Figure 21

Quote 35 from CVF Member

In my correspondence with my MP, I expressed deep frustration and concern over the delayed vaccination for children, even after approval was granted. By December 2021, despite assurances that children were less affected by the virus, our friends suffered the heartbreaking loss of a child with the same genetic condition as my daughter. This tragedy, which we believe was potentially preventable with earlier vaccination, highlights the unacceptable delay in administering vaccines to children, over a year after healthy adults had the chance to have been vaccinated two or even three times. Despite having the official go-ahead, we struggled to find someone to vaccinate our 11-year-old daughter. It wasn't until January 2022, during a hospital stay for another illness, that a senior paediatric consultant managed to arrange her vaccination. The delay had posed a significant risk, as she could have contracted the virus during that time. This period was especially stressful, with vulnerable under-12s without vaccination, yet required to attend school. As a parent of a child with disabilities, I faced a dilemma: risk her health at school or hinder her development at home. The government's apparent disregard for clinically vulnerable children's safety during this critical time was both alarming and disappointing. [The correspondence referred to is exhibited as **Exhibit LWCF/87 - INQ000420547].** Anon Member

171. Some of our families were troubled by the smaller doses particularly if they had a larger child, or an older 11-year-old who may have been close to accessing a full adult dose, as they felt it was likely to be more efficacious. These concerns continued as the lower doses were given subsequently to children who had turned 12 even for their third doses, as boosters, shown in figure 22 below.



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new variant). Emerging evidence also suggests that countries with longer schedules (eight to twelve weeks) may have a lower rate of myocarditis after the second dose. Although this latter evidence is limited, JCVI have taken a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis.

Children aged 5-11 years

Children at higher risk of severe COVID-19

Children and young people aged 5 to 11 years who are in recognised risk groups (table 4) should receive two doses of the paediatric dose (10μg) of Pfizer BioNTech vaccine at an interval of at least eight weeks. This group would also include those children who are about to commence immunosuppression (see below).

Children aged 5-11 years who are contacts of immunosuppressed individuals

Individuals aged 5-11 years who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals of any age who are immunosuppressed (defined in tables 3 and 4) should be offered two doses of the paediatric dose (10μg) of Pfizer BioNTech vaccine at an interval of at least eight weeks.

Other children aged 5-11 years

A decision on the vaccination of children aged 5 to 11 years who are not in recognised risk groups is pending further consideration by JCVI.

Figure 22

172. **Accessibility.** CVF members felt that accessibility was well supported for this cohort, specifically for the first doses. CVF members were greatly appreciative of the meticulous attention to detail evident at many clinics. There was a clear understanding of the importance of providing comprehensive support to these children, where the process was highly accommodating. Members observed the thoughtful planning and consideration given to a variety of special needs, and, as a result, children generally responded positively to the welcoming and supportive atmosphere created by healthcare teams. The stickers and certificates were also very well received, the only complaint from the children on that front was that there was no new sticker offered for

second and subsequent doses. Some families pointed out that second and subsequent doses were not as well supported.

Quote 36 from CVF Member

"For the first dose they had trained staff, kid friendly venues etc but nothing second time."

Jay, aged 49

173. **Booking appointments.** On 16 February 2022, the JCVI announced that "Parents and guardians should wait for the NHS to contact them for when it is their child's turn to get the life-saving vaccine with local NHS teams already contacting those who are eligible." **[Exhibit LWCF/86 – INQ000420546]** But frequently our families found that they were not being identified and that they had to actively pursue vaccine doses. Once again CVF members found themselves stuck in what had become a very familiar loop due to confusion within the NHS regarding children's vaccines.

Quote 37 from CVF Member

"I asked the GP but they didn't know anything and said to phone 119. 119 said to phone the GP. A lot of us had the same problem."

Nikki, aged 50

174. This issue of getting children flagged on the computer system persisted for clinically vulnerable families throughout the rollout to priority children. It was a particular problem for children who qualified for doses based on a third party. GPs and the NBS often lacked a clear understanding of processes needed to assist our families in several critical aspects:

a. Priority Group Identification: Many GPs and NBS staff were unsure of how to flag children, particularly as household contacts of severely immunosuppressed people.
b. Appointment Booking: Families faced difficulties in accessing information about how to book vaccination appointments for their children. GPs and the NBS were often unable to book appointments.
c. Information on Vaccine Availability: GPs and the NBS were frequently unable to provide information about the locations where paediatric doses could be obtained.

175. Parents / carers who were the least able to advocate for their children were significantly disadvantaged. If a child was not flagged, they would not be invited for vital doses.

CVF believes that there is a need for improved communication within the NHS to update GPs and the NBS on new processes. Also, immunosuppressed people or parents / carers of immunosuppressed children should have been contacted and invited to identify their own household contacts.

176. Aware of the challenges faced by families with children eligible for priority vaccines, Dr Ben Burville, on 3 February 2022, posted on Twitter (now X) to extend an invitation to *"any qualifying children from anywhere in the country"* to attend their *"dedicated 5-11yr old clinic*", shown in figure 23 below. Following this, Coguet Medical Group also expressed their enthusiasm via an announcement on 8 February 2022, shown in figure 24 below, that they were *"excited to be vaccinating eligible 5-11 year olds from around the country today!"*. Members of CVF expressed deep gratitude for this initiative. However, CVF remains concerned, noting that the need for individual clinics to extend such offers is a troubling indicator of significant shortcomings at the national level in ensuring adequate vaccine access.

Figure 23

Figure 24

177. **Vaccine tourism and Inequalities.** The experiences within the 5 to 11-year-old age group appeared to be quite diverse. Once vaccine centres became available, the process became more straightforward for some. However, there were many who struggled, and some families reported having to travel over 100 miles within the UK to get their children vaccinated. Not all vaccination centres offered doses for younger children and even 'Green lighted' centres had different offers available to different age groups of children.

178. Members of CVF, particularly those who had withdrawn their children from school early in the pandemic, were keen to do what they could to return their children to school safely. In some cases, families who had the financial means, opted to travel to countries in Europe or the USA where vaccines were available sooner.

Quote 38 from CVF Member

"I've had nothing but trouble trying to get my ten year old vaccinated, our GP surgery has not run a vaccine clinic for 5-11 and said they weren't going to, the CCG said they were trying to get it sorted but nowhere to store the vaccines. Friday our GP surgery sent this on a random list of children (friends got it who are not vulnerable and the children wouldn't have been eligible yet). I drove over an hour to get him vaccinated and yet they have surplus stock going out of date 5 minutes down the road & why not use them to do the eligible children first!" (Posted to CVF on 28th March 2022)

Lauren, aged 46

179. **Second doses.** Some clinically vulnerable 5 to 11 year-olds were due second doses before many healthy children were offered their first ones. As seen in figures 25, 26 and 27 below, which are screenshots taken by a member of CVF on 31 January 2022.

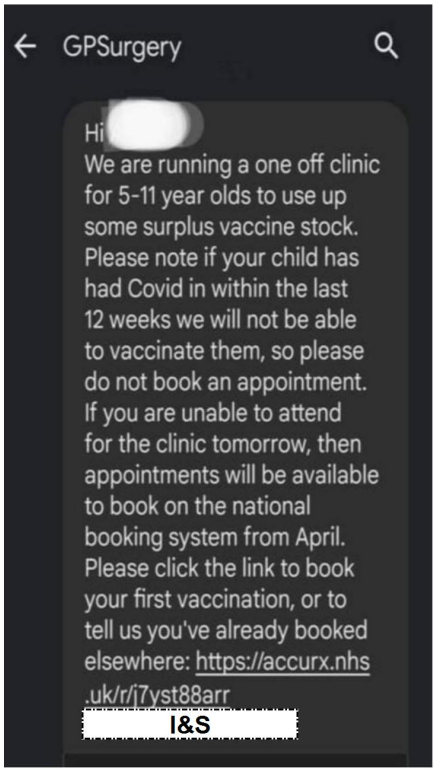

Figure 25

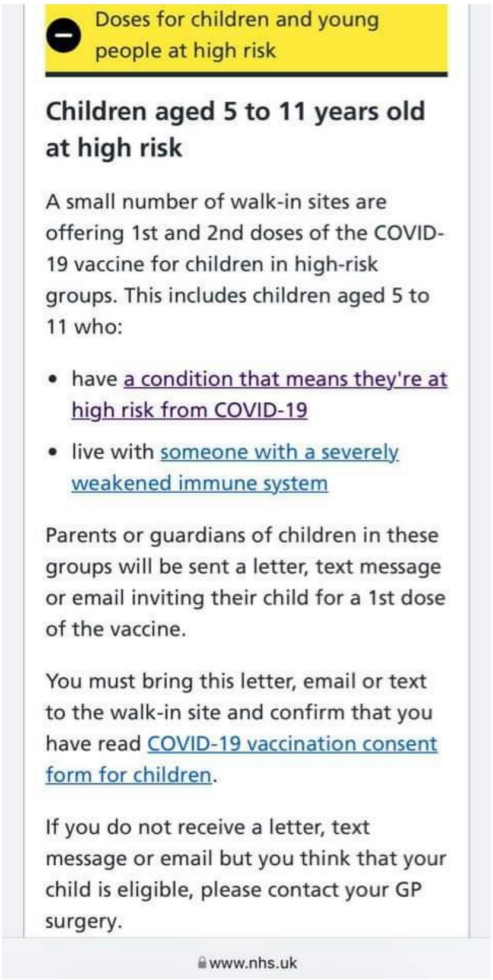

Figure 26

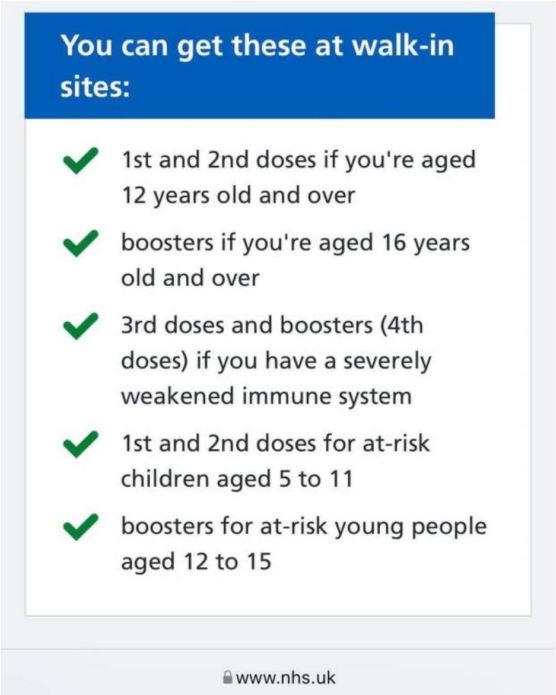

Figure 27

180. As mentioned earlier, these vulnerable children were welcomed with far less support, which made the experience more challenging for SEN children.

181. Families often discovered that accessing vaccines became significantly easier when walk-in centres were made available to healthy children. However, this also meant that vulnerable children and vulnerable households were exposed to unmasked families, some of whom were exhibiting symptoms potentially putting them at risk, which made the experience particularly stressful for all of our families, but especially for those who were still strictly shielding.

182. Additionally, on 22 February 2022, Lorna Fillington, a member of CVF, was invited to speak on Sky News via CVF. As a parent of a high-risk child aged 5 -11, she expressed some of CVF's concerns regarding clinically vulnerable children aged 5 -11, who would not be fully vaccinated at the time the 'Living with Covid' policy was set to be implemented and protective measures were to be withdrawn. Clinically vulnerable children would be expected in schools, without mitigations, and without the free lateral flow testing it was clear that Covid-19 was to be treated as 'just a cold'.

Quote 39 from CVF Member

"I chased it up with my CCG again and again. I had to chase every single one of our various 8 doses up until that point. My CCG hadn't appeared to have thought about second doses at all; planned to hold no clinics; and had no walk-in centres for 5-11."

Carly, aged 44

183. **Boosters.** First booster doses were given in Autumn 2022. As identified above, families with older and larger children were concerned about the fact that 12-year-olds were frequently offered the paediatric formula, despite being old enough to qualify for the 30µg 'adult' dose.

Quote 40 from CVF Member

"I was extremely happy and grateful to get my son vaccinated. But he was a heavy 11 year old. I was really bothered by the dose (10µg) being a third of the 12-15 dose (30 µg). Even though he was 12 at the time of his booster, he still had to be boosted with the lower dose. f I wasn't so desperate, I'd have waited until he turned 12 so all of his

doses were 30 µg. I know it's tested, and children are less susceptible, but surely it doesn't give the same protection?
Justin, aged 50

184. When it came to children's vaccines there were a number of inconsistencies in the overlapping protocols which led to confusion for both parents and healthcare professionals.

Quote 41 from CVF Member
"I was told my child couldn't have a booster after turning 12, and I was unable to book him in online. So, I printed off the green book, waited 6 months and tried a walk-in centre. They had zero adult vaccinations spare. So they discussed whether he could have a child booster. Apparently because he had had two doses of the childrens vaccine, he could have that again. So we got ready to have it. They asked then if we had had Covid in the last 3 months. I said yes but I thought it only had to be 28 days. Apparently, that's correct for an adult. So I said but he's over 12, therefore eligible for an adult vaccine. Oh no, they said he's 12 so a child! Errm?! I said but if you had adult vaccines you would now be giving him an adult vaccine, so can't he be vaccinated under 28 day adult rules. Oh no they said, because he's still a child!! Arrghh!
I told them but what if he gets offered a vaccination through school as a Year 8 aged child - oh well their rules may be different!!!'
I have to say the staff did try to work it out and you could see them scratching their heads for logic!
Tina, aged 43

185. Children aged 5 to 15-years old who qualified for boosters due to living in a household with someone with a weakened immune system could not book doses via the NBS. They could only access doses via a walk-in clinics or GPs surgeries (see figure 28 below).

Figure 28

186. Once again, CVF members found that the needs of their families were not recognised, and a general confusion amongst healthcare professionals regarding their qualification for vaccination combined with a lack of paediatric doses meant that the process was challenging. Figure 29 below shows the paediatric formula protocol updated ready for universal 5 to 11-year-olds roll out, valid from 31 March 2022.

Recommended primary dose schedule by age and risk status.

Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine
Primary course for children who are not in a risk group

Age	Doses	Advised Minimum Interval	Recommendations
5 years to 11 years (one-off programme, see Dose and frequency of administration), not in clinical risk group nor sharing living accommodation with an immunosuppressed individual of any age	2	12 weeks	This one-off programme applies to those currently aged 5 to 11 years, and children will continue to become eligible as they turn five years of age until the end of August 2022.
12 years and under, in school year 7	2	12 weeks	

Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine
Primary course for children in a risk group

Age	Doses	Advised Minimum Interval	Recommendations
5 to years of age and sharing living accommodation with an immunosuppressed individual of any age	2	8 weeks	Those aged 12 years may also be vaccinated under this protocol to commence or complete a course with Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine in accordance with the recommendations in Chapter 14a.
5 to 11 years of age[12] in an at-risk group	2	8 weeks	
5 to 11 years of age[12] and had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule	3	8 weeks	

Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine should be offered to children aged 5 to 11 years[4] and some children aged 12 years in accordance with the recommendations in Chapter 14a.

At the time of writing, this includes:

- all children aged 5 years to 11 years (one-off programme, see Dose and frequency of administration)
- children, aged 12 years and under, in school year 7
- children aged 5 to 11 years in a clinical risk group (as defined in Chapter 14a)
- children aged 5 to 11 years who are a household contact of someone who is immunosuppressed (as defined in the Chapter 14a)
- children aged 12 years, who commenced but did not complete a primary course of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine

Figure 29

187. **Removal of under 11s from Booster lists.** CVF members were incredibly concerned that children aged 11 and under in severely immunosuppressed households were excluded from the Green Book in Autumn 2023. The decision is particularly troubling because vaccination reduces transmission and in combination with the fact that school classrooms are high-risk environments for Covid-19 infections. Classrooms are especially high-risk settings because children under 11 are among the least vaccinated populations; their generally poorer hygiene practices and their ability to express concerns regarding health make them more likely to attend schools infected. Also, classrooms breach all three of the WHO's "3Cs" for Covid-19 transmission:

a) they are often “crowded”
b) they involve “close-contact settings where people have close range conversations”
c) and are “confined and confined enclosed spaces with poor ventilation”.
d) As the WHO further explains, in figure 30 below, “The risk is higher in places where these factors overlap.”

Figure 30

Healthy individuals

188. The very public decision-making process that surrounded the Covid-19 vaccine offer to healthy 5 to 11-year-olds raised concerns.

189. On 13 February 2022, it was widely reported that the JCVI had reached an impasse with the government **[LWCF/88 – INQ000420548]**. By 15 February 2022, Wales announced that it would be vaccinating 5 to 11-year-olds **[LWCF/89 – INQ000420549]**. Shortly thereafter, the JCVI published a statement on 16 February advising a "non-urgent offer of two 10 µg doses" **[LWCF/90– INQ000257287]**. That afternoon, Scotland announced that they would also be offering vaccines to healthy children in this cohort **[LWCF/91 – INQ000420551]**.

190. CVF believes that the cause of the low vaccine uptake in this age group stems from the following aspects of the vaccination program's implementation and communication:

    a. The decision-making process for the Covid-19 vaccine offer to healthy 5 to 11 year-olds in the UK was rooted in several key aspects. The JCVI's approach was clarified in their statement on the vaccination of children aged 5 to 11 years **[Exhibit LWCF/90 – INQ000257287]** which took an exceptionally cautious approach, focusing on the potential direct health benefits and harms, as well as the indirect educational impacts of vaccination. This caution may have contributed to a public perception of uncertainty or hesitancy regarding the vaccine's necessity and benefits for this age group.

    b. Additionally, an article published in the British Medical Journal **[Exhibit LWCF/92 – INQ000420553]** noted that the UK's decision to selectively vaccinate adolescents, including the 5 to 11 year-old age group, positioned it as an outlier among rich countries. This difference in approach compared to other countries might have influenced public perception and confidence in the vaccine program for children, potentially affecting vaccine uptake.

    c. The cautious and selective approach, along with the detailed deliberation and caveats that came alongside vaccine offers, may have led to lower vaccine uptake in this age group in the UK, especially when compared with other countries which were more proactive. The decision-making process was far more public than other age categories, and this could have influenced parental decisions about vaccinating their children. In the view of CVF, this seemingly led to a much lower

vaccine uptake in this age group, especially when compared with other similar countries.

191. **Differences across the UK.** While England and Northern Ireland fell behind Scotland and Wales, some vulnerable families with the financial means opted to travel to access vaccines, as there was no certainty that they would ever be made available to them. It was not until 4 April 2022, that all children in this age group were able to receive Covid-19 vaccines. Bookings via the NBS were possible in advance of the rollout, from 2 April 2022 **[Exhibit LWCF/93 – INQ000420554]**. Figure 31 below, shows the messaging from the Public Health Agency regarding the 5-11 childhood vaccination programme.

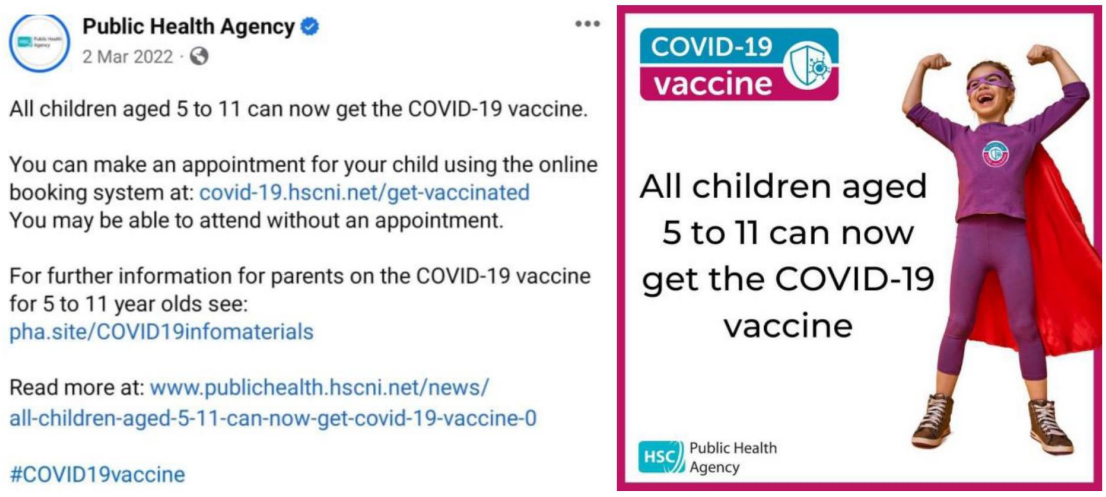

Figure 31

192. Northern Ireland did not offer national bookings until 2 March 2022. CVF members from across the UK, but particularly from Northern Ireland, chose to access vaccines across the border in the Republic of Ireland as they were available considerably sooner as they were approved on 23 December 2021 for distribution from 8 January 2022

193. **School-based Covid-19 Vaccination Programme.** The JCVI statement, released in February 2022, strongly suggested that future vaccinations for 11-year-olds should be administered through a school-based program, recognising the potential to reduce inequalities through this approach. However, CVF notes that the Department of Health did not utilise this approach to administer initial vaccine doses or indeed ultimately offer any schools-based programme.

"For deployment: this one-off programme applies to those currently aged 5 to 11, including those who will turn 5 years of age by the end August 2022. Based on current evidence, on-going eligibility for vaccination is expected to be for children aged 11 years and offered during the early part of the relevant academic year (year 7 in England and Wales, year S1 in Scotland, and year 8 in Northern Ireland). Children in these academic years in 2022/23, even those who are already aged 12, may be vaccinated using the paediatric formulation to support operational simplicity and to reduce the expected risk of reactogenicity which may interrupt education."

…

"From UK experience with previous paediatric immunisation programmes, vaccine deployment via school-based approaches is associated with higher levels of vaccine coverage with less inequality as measured by ethnicity and indices of deprivation." **[Exhibit LWCF/90 – INQ000257287]**

194. **Second dose.** While this cohort was eligible for second vaccine doses, the uptake remained low, and unlike adults and older vaccine groups, public messaging promoting vaccines to families was notably lacking. Only 2.1% were recorded as having taken up second vaccines (see tables in para 195), CVF believe that these would have been predominantly clinically vulnerable children or children in clinically vulnerable households

195. **Boosters.** Boosters were never offered to healthy 5 to 11-year-olds.

196. The tables below summarises the uptake of each dose of the vaccine [Full dataset can be found at **Exhibit CF/55**] as taken from the ONS dataset on vaccination rates among different age groups:

28/02/22[9]	First dose uptake (%)	Second dose uptake (%)	Third dose uptake (%) *available to Priority groups only
5 to 11-year-olds	7.8	2.1	N/A (available after 28/2/22)

[9] This is the latest date that data was captured within the timeframe being considered by the Inquiry.

16/08/23[10]	First dose uptake (%)	Second dose uptake (%)	Third dose uptake (%) *available to Priority groups only
5 to 11-year-olds	9.4	6.3	0.2

(iv) 6 months to 4-year-olds

197. CVF acknowledge that this group is currently outside the timeframe and therefore scope of the Inquiry. Nonetheless, CVF firmly believe that, for the sake of thoroughness and in the pursuit of learning lessons (as a future pandemic would need to consider the vaccination of all age groups, not just those which (arbitrarily) fall within the Inquiry's terms of reference), it is essential to include them for the Inquiry's consideration to ensure that their experiences are not overlooked.

Priority groups.

198. The 6 months to 4 years clinically vulnerable group almost certainly constitutes the smallest cohort eligible for vaccination. Children in this age range are generally considered healthier, as health conditions tend to accumulate with age. Nevertheless, it is important to emphasise that despite the widespread perception that these young children are at minimal risk, we must not ignore the need to protect those who do face sometimes significant risks.

199. The majority of infants who qualified in this category were born since the evolution of Covid-19.

200. Some clinically vulnerable children may have serious or congenital conditions that may not necessarily be life-limiting, but, in combination with the presence of this new threat has significantly impacted their quality of life. Many of these children had spent their entire living memory shielding, waiting for protections and increased freedoms offered by vaccines. Parents will do everything in their power to protect their vulnerable children, and so the consequences of this prolonged wait affected entire households.

201. Whilst the UK made headlines around the world for streamlining and prioritising their approvals process for adult vaccines, CVF wish to highlight that the needs of children

[10] This is the date that the most current data was captured that is outside the timeframe being considered by the Inquiry.

were very much an afterthought as no such streamlining took place for children. Healthy young infants across Europe **[Exhibit LWCF/94 – INQ000420556]** and the USA **[Exhibit LWCF/95 – INQ000420557]** were able to access multiple safe, approved vaccines from aged 6 months and up almost one whole year (available in the USA from 18 June 2022) before clinically vulnerable children were offered their first doses in the UK (available from 12 June 2023). **[Exhibit LWCF/96 – INQ000420558]**.

202. **Lowest Dose**. Infants (aged 6 months to 4 years) are vaccinated with a 3 microgram (µg) dose, less than a third of the 10 µg dose given to those aged 5 and over. **[Exhibit LWCF/97 – INQ000420509]** Once again, families were troubled by the smaller doses, particularly if they had a 4-year-old attending primary school, all of whom are significantly bigger than a 6-month-old infant.

203. **Availability**. Parents faced numerous challenges when trying to secure vaccines for their children, as many Primary Care Networks ("PCNs") did not support the vaccination rollout. Families could not simply book vaccine appointments through the NBS. Instead, they had to rely on being contacted and invited for vaccination appointments, which some families found did not happen.

204. There appeared to be a lack of public health messaging and an absence of signposting from healthcare professionals, both of which exacerbated the situation. Parents felt there was a reluctance, resistance, or apathy from healthcare providers when it came to vaccinating children in this age group. Even proactive and well-informed CVF members reported their experiences accessing doses for this age group was even more challenging than vaccinating their older children. Some of them ultimately failed to access (UK) doses due to the difficulties they faced.

Quote 42 from CVF Member

"I have absolutely no idea how clinically vulnerable children under 5 can access covid vaccines, even though it was announced they were finally authorised from mid-June 2023 - it's a small cohort so government don't want to help them, it seems no one does. Relief came when my son recently turned 5, I thought it would be easy the same as it was for those healthy 5 year olds who could just walk in to a pharmacy with their parent and grab their jabs. Or even better, maybe we could be offered an appointment at a quiet clinic now that the rest of the nation had been seen to. But no, I looked around and no one was there to help. Not a single person in our whole district is doing covid vaccinations for under 12's now.

Even a local paediatrician doesn't know anything about Covid vaccines. A whisper of hope came when I discovered someone in a neighbouring district starting vaccinations for those aged 5+ mid October 2023 and I grabbed their very first slot. I patiently stood outside with my son in my arms for 40 minutes. I thought we'd be celebrating but the air turned cold as I was told that's it, there's no appointment in 8 weeks time for his 2nd primary dose, nor a booster 3 months later. We are now back at home waiting for him to get all 3 doses… it looks like I will have to wait another year to continue his schedule, or if we are lucky they may do one dose in spring."
Anon Member

205. **Vaccine tourism and Inequalities**. Significant delays to vaccine approvals and availability left families, particularly those with children of school age, with no vaccine options. CVF members with both clinically vulnerable or healthy children decided to travel to access doses. Both the Republic of Ireland and Germany were favoured choices.

Quote 43 from CVF Member
"Myself and my wife, have primary immune deficiencies. I additionally have recently been diagnosed with an autoimmune condition. As a result of our immune deficiencies, our daughter has been under the care of paediatric immunology, from birth.
We have been extremely concerned regarding the lack of any protections for CV families and children. We were hopeful, when the US announced vaccination of children 6 mths – 4 yrs, that they would become available in the UK.
Instead, we watched on while many other countries made them available, for children. The UK did not follow suit.
We decided, as many other families did, that we would drive to Germany in order for our daughter to receive her covid vaccinations. We have just returned to Germany for a third time. The Doctor was baffled by the fact that she could not obtain a vaccine in the UK. He confirmed that we were welcome to return."
Amos, aged 44

Quote 44 from CVF Member
"As my vulnerable child was under 5 years old and due to start school at 4 years old in September 2022, I felt very worried that there was no vaccination available for this age group. This is not to say there was not a vaccination available, in fact Pfizer by then had a vaccination for under 5's which was used in the US and other countries such as Germany. We decided to take our daughter to Germany for vaccination through an

organisation set up by the German people to help people like us to access vaccination for our child. The vaccination itself was free. I had to contact a coordinator group who informed us of everything. All we had to do was book our travel and accommodation. We have returned to Germany on three occasions to vaccinate our child. Our child suffered no side effects and started school. Despite being vaccinated, our child caught Covid within 6 weeks of starting school and was quite poorly with it. However, he was not admitted to hospital and for that I am surely grateful to the vaccination. I know of many other parents of children under 5 years who have travelled to Germany for their compassionate vaccination programme. However, it's such a crying shame this could not be done in the UK." May 2023
Maria, aged 39

206. **Patient Group Direction (PGD)**. The 6 months to 4-year-old cohort was the only vaccination group to not have a formal national protocol or a PGD:

"A national protocol and a patient group direction (PGD) will not be published for this cohort."

In its place, there was said to be local patient specific direction (PSD):

"Due to the relatively small size of this cohort and associated settings for vaccination, administration of this vaccine to eligible children will be via a local patient specific direction (PSD)." **[LWCF/96 – INQ000420558]**

207. The decision to administer vaccines to the 6 months to 4-year-old cohort without a formal national protocol or PGD and instead rely on local PSDs caused the following inequalities and challenges for clinically vulnerable families:

a. Inequalities: The lack of a national protocol would result in variability between different healthcare facilities. CVF believe this could have affected the consistency and quality of care their children received.

b. Access to Local PSDs: Families faced increased challenges in accessing local PSDs as each child needed to be assessed on an individual basis for vaccines to be approved. This was especially difficult for children in remote or underserved areas. If healthcare workers were not familiar or confident to make decisions a vulnerable child is at greater risk of missing out on a safe and protective vaccine.

c. Advocacy: Clinically vulnerable families needed to become even stronger advocates for their children's healthcare, in order to ensure that they received the recommended vaccinations and when it came to monitoring for any potential side effects.

208. CVF would like the NHS to prioritise clear communication, identification, and access for clinically vulnerable families, ensuring they experience a smoother, fairer process. CVF believe that it remains important for the NHS to closely monitor the administration and uptake of vaccines to this cohort to address any issues that may have arisen from not have a formal national protocol or a PGD for these very young children.

209. **Immunosuppressed Households**. Unlike all previous age cohorts, healthy young children in a household with a person with a weakened immune system never qualified for vaccines. Indeed, subsequently following the end of the Autumn Booster Campaign in 2022, on 12 January 2022 it was decided to withhold vaccines to all healthy children under the age of 12 in an immunosuppressed household, depriving their high-risk household members a vital protective barrier. Figure 32 is an example of communication that we received stating that children who turned 5 on or after 1 September 2022 could only book a first or second dose of a Covid-19 vaccine online if they are at high risk due to a health condition or because of a weakened immune system. CVF are aware that households with immunosuppressed members and children aged under 12 years, who can afford to do so, are now actively seeking vaccines abroad.

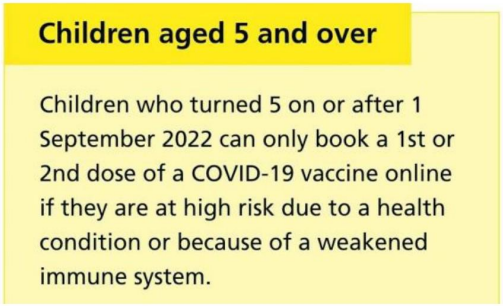

Figure 32

Quote 45 from CVF Member

"We discussed, with her immunologist, the absurdity of the situation that a child over 12 in a CV family could receive a vaccine but one under 12 could not. He agreed that it was an anomaly and was sympathetic.

Alex, aged 37

Healthy individuals

210. Healthy children born after 31 August 2017, have been deprived of the opportunity to receive any Covid-19 vaccines since 1 September 2022. This stands in contrast to the decisions made in many other comparable countries, where Covid-19 vaccinations have been actively promoted as safe and effective components of their standard paediatric vaccination schedules. Figure 33 below a screenshot from the NBS website taken on 25 October 2022 stating that you could get a first and second dose of the Covid-19 vaccine from a walk-in site if you are aged 5 years or over, and turned 5 on or before 31 August 2022.

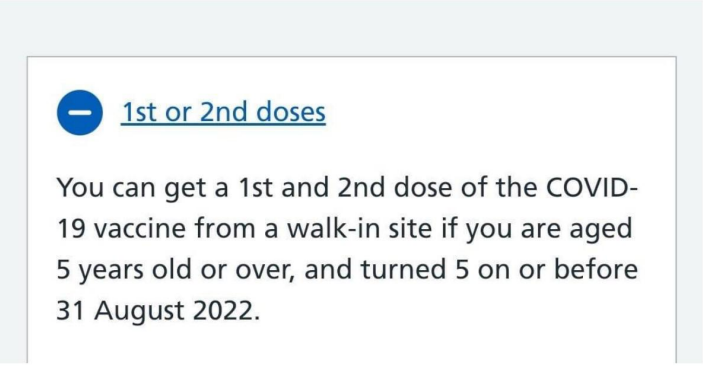

Figure 33

211. **Risks To Unvaccinated Younger Children.** We observed a concerning trend of ICU / HDU admissions in early 2023 for 0 to 4 year-olds, evident in the ONS data. During that week, the data suggested that the risk for young children was equivalent to the risk faced by the highly vaccinated 65 to 74 year-old category. **[Exhibit LWCF/98 – INQ000420510]** is the ONS dataset from week ending 22 January 23, showing the age range of those in intensive care units (ICU) and high dependency units (HDU) in respect of Covid-19. Figure 34 below illustrates that the 0 to 4 year-old category and the 65 to 74 year-old category had a very similar admission rate.

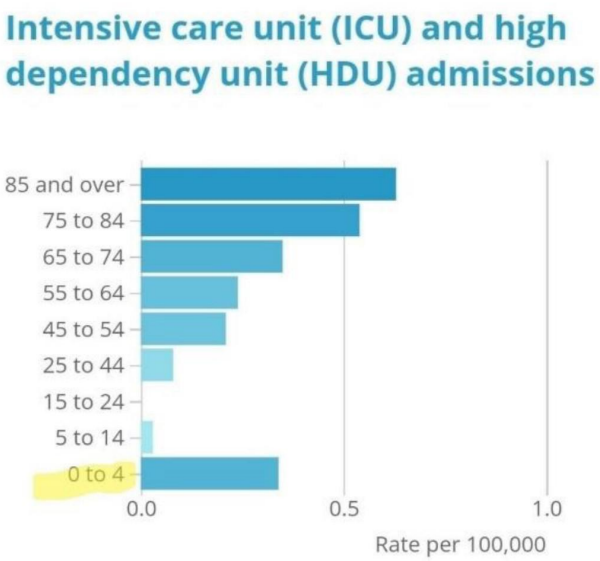

Figure 34

212. Professor Christina Pagel picked up on CVF's concerns and delved deeper into ONS data for this age cohort over the previous year. She discovered that the average risk for this group was comparable to that of individuals in the 45 to 54 year old age range many of whom had received multiple vaccinations. She tweeted on this subject on 3 February 2023 with illustrative graphs, which can be seen at figures 35 and 36 below

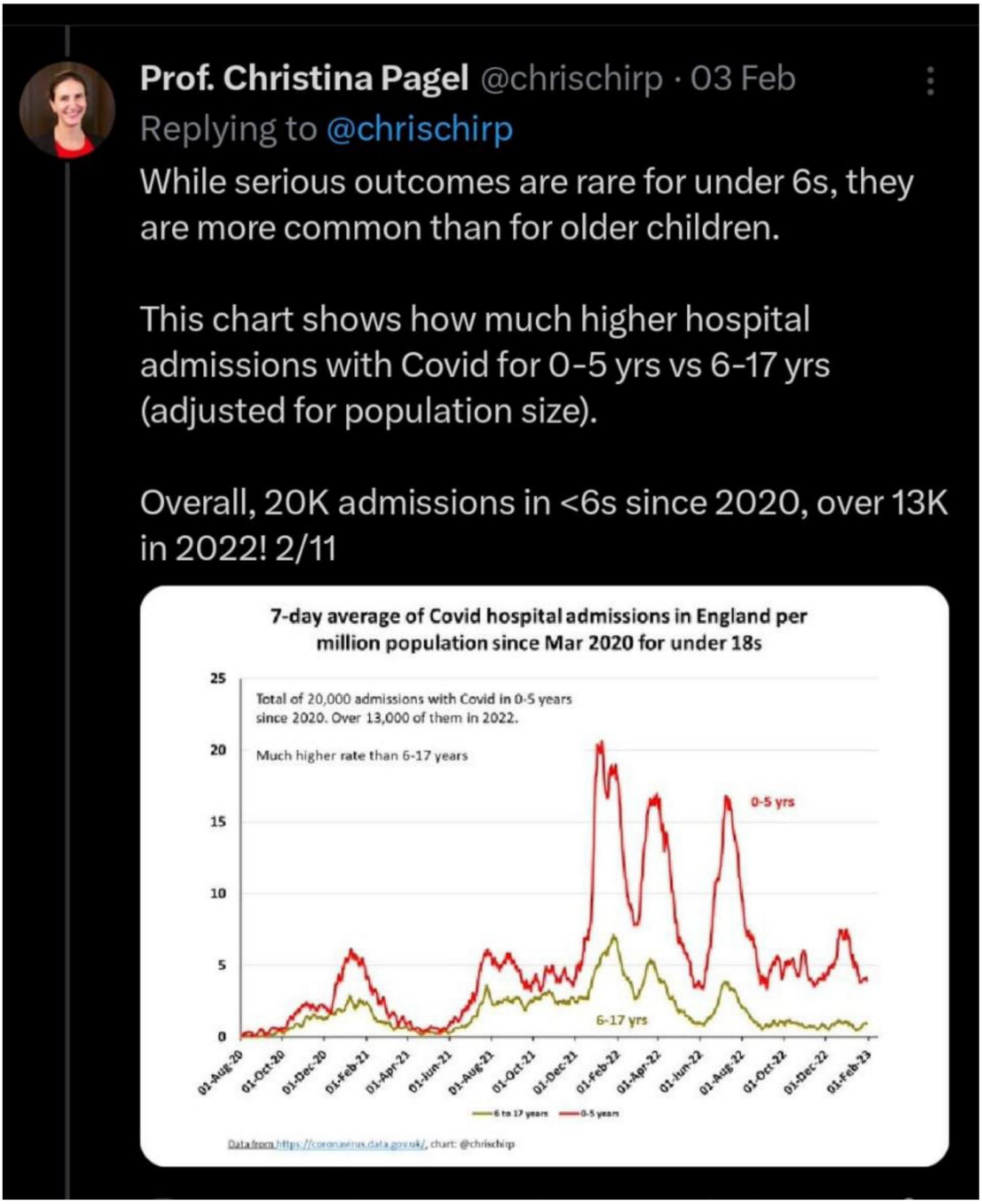
Prof. Christina Pagel @chrischirp · 03 Feb
Replying to @chrischirp
While serious outcomes are rare for under 6s, they are more common than for older children.
This chart shows how much higher hospital admissions with Covid for 0-5 yrs vs 6-17 yrs (adjusted for population size).
Overall, 20K admissions in <6s since 2020, over 13K in 2022! 2/11
7-day average of Covid hospital admissions in England per million population since Mar 2020 for under 18s
Total of 20,000 admissions with Covid in 0-5 years since 2020. Over 13,000 of them in 2022.
Much higher rate than 6-17 years
0-5 yrs
6-17 yrs
25
20
15
10
5
0
01-Aug-20
01-Oct-20
01-Dec-20
01-Feb-21
01-Apr-21
01-Jun-21
01-Aug-21
01-Oct-21
01-Dec-21
01-Feb-22
01-Apr-22
01-Jun-22
01-Aug-22
01-Oct-22
01-Dec-22
01-Feb-23
6 to 17 years
0-5 years
Data from https://coronavirus.data.gov.uk/, chart: @chrischirp

Figure 35

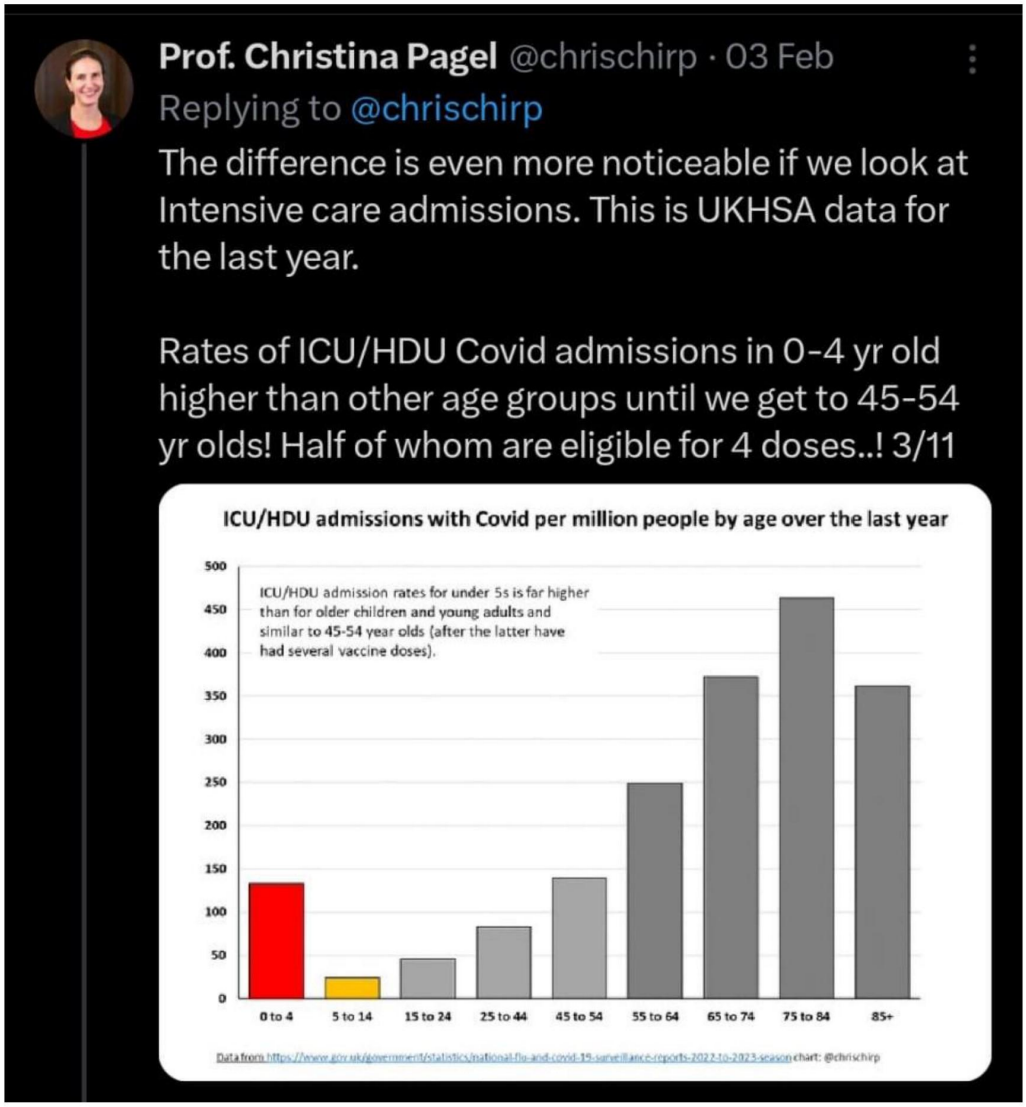

Figure 36

213. She stated that "*whilst serious outcomes are rare for under 6s, they are more common than for older children*" and that overall, there had been 20,000 hospital admissions in under 6's since 2020 and over 13,000 in 2022. She went on to say that the difference was even more noticeable if you look at intensive care admissions and the UKHSA data for last year showed that rates of ICU/HDU Covid admissions in 0 to 4 year-olds were higher than other age groups until you get to 45 to 54 year-olds.

214. A pre-print research paper co-authored by Harrison Wilde, Professor Pagel et al (yet to be published[11] and discussed in more detail in paragraph 216) illustrates that the

[11] We have express permission by Professor Pagel to include reference to this within our statement.

percentages of admissions (both general and ICU) for children and young people have increased over time.

215. The data covers all of England up to September 2023 and is a follow up to a paper *'Hospital admissions linked to SARS-CoV-2 infection in children and adolescents: cohort study of 3.2 million fist ascertained infections in England' BMJ 2023;382:e073639* published in the BMJ on 18 May 2023 **[Exhibit LWCF/99 – INQ000420511]**. Professor Pagel explains this article on child covid hospital admissions to provide more background and highlights the need for children's vaccines **[Exhibit LWCF/100 – INQ000420512]**.

216. The pre-print research paper co-authored by Harrison Wilde, Professor Pagel et al presents findings that are particularly relevant to CVF's focus on child health and wellbeing. Key points that we would like to highlight are:

    a) Increase in Hospital Admissions Among Under-1s: There has been a noticeable rise over time in the percentage of both general and ICU hospital admissions in children under one year old. A recent study **[Exhibit LWCF/101 – INQ000474488]** led by Harrison Wilde et al. identified a marked increase in the proportion of Covid-related hospitalisations among infants, who remain the most affected paediatric group in England, as they are particularly vulnerable. Notably, since 2022, infants now represent nearly 49% of paediatric Covid-19 admissions, likely due to their limited prior exposure and immunity to Covid-19, as vaccination has improved outcomes for older age groups. The study highlights concerns that infants generally lack direct or indirect protection from vaccines, despite being inherently more susceptible to severe respiratory illnesses.

    b) Consistently High Admission Numbers: The number of hospital admissions in this age group has remained high throughout the observed period (1 July 2020 to 31 August 2023). This indicates a sustained level of risk or vulnerability in infants.

    c) Lower Prevalence of Underlying Health Conditions: Interestingly, the percentage of these young patients admitted with pre-existing health conditions is lower compared to other age groups. It could imply that their hospital admissions are more directly related to acute conditions rather than chronic health issues. It also means that, in the view of CVF, all infants must be considered as clinically vulnerable.

d) Comparatively Short Hospital Stays: Despite the vulnerability of under-1s, their hospital stays tend to be relatively short, especially when compared to admissions for other respiratory viruses like RSV ('Respiratory Syncytial Virus'). This might reflect the nature of their illnesses or the effectiveness of treatments they receive.

e) Infants under one year old are more susceptible to hospital admissions for Covid-related issues for several reasons:

   i. The vast majority of infants in this age group are not classed as clinically vulnerable under the current guidance and therefor do not have access to Covid-19 vaccines, leaving them unprotected.
   ii. Being their probable first encounter with the virus, they lack prior immunity.
   iii. Infants are inherently more susceptible to respiratory infections, which can be severe in this age group.

f) There was a significant reduction in hospitalisations among vaccinated children, with the most recent data indicating that over 94% of hospitalised children are unvaccinated. The study examined children with clinical risk factors and found that approximately 25% of them had a Green Book (clinically vulnerable) risk factor. Clinically vulnerable children appear to be disproportionately overrepresented compared to the general population as another study had identified that 8.3% of school age children were at risk, although, concerningly, 75% of hospitalised children had no known risk factors.

"On 5 March 2019, 24.4% of the UK population were at risk due to a record of at least one underlying health condition, including 8.3% of school-aged children"
[Exhibit LWCF/102 – INQ000420513]

217. In CVF's view, these findings have identified unique health needs and vulnerabilities of infants, especially in the context of ongoing and emerging health challenges like Covid-19. This information must be used to guide the JCVI to reconsider its approach to the vaccination of children and infants to better protect and support the health of the youngest and most vulnerable children.

218. CVF has produced a schedule setting out the dates that Covid-19 vaccines were approved for each age group, and the dates the vaccine was rolled out to children within those age groups in England, Northern Ireland, Scotland and Wales:

Age	USA, CDC (ACIP) recommend use of vaccine	Europe, EMA / European Commission (EC) approval	UK, MHRA approval	Clinically Vulnerable Rollout ENG	Healthy Rollout ENG	Time between
16-17 years	12/12/2020 https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?s_cid=mm6950e2_w **[EXHIBIT LWCF/103 – INQ000420514]**	21/12/2020 https://www.eu2020.de/eu2020-en/news/article/european-commission-approves-first-covid-19-vaccine/2430420 **[EXHIBIT LWCF/104 – INQ000420515]**	2/12/2020 https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine **[EXHIBIT LWCF/48 – INQ000420516]**	With adults – Group 4 (CEV) https://www.independent.co.uk/news/health/covid-vaccine-rollout-over-70s-clinically-extremely-vulnerable-b1788649.html **[EXHIBIT LWCF/105 – INQ000420517]** Group 6 (CV) https://www.england.nhs.uk/2021/02/nhs-offers-covid-jab-to-clinically-vulnerable-and-people-65-to-69/ **[EXHIBIT LWCF/106 – INQ000420518]**	15/8/2021 https://www.gov.uk/government/news/all-young-people-aged-16-and-17-in-england-to-be-offered-vaccine-by-next-week **[EXHIBIT LWCF/107 – INQ000420519]**	MHRA approval and Healthy Rollout ENG **256 days**
12-15 years	12/5/2021 GRADE:	28/5/2021 https://www.	4/6/2021 https://www.	19/7/21 Severe	13/9/2021 https://ww	MHRA approval and

	Pfizer-BioNTech COVID-19 Vaccine Age 12-15 Years | CDC **[EXHIBIT LWCF/108 – INQ000469894]**	ema.europa.eu/en/news/first-covid-19-vaccine-approved-children-aged-12-15-eu **[EXHIBIT LWCF/109 – INQ000469895]** No EC approval before vaccinations began Germany https://www.dw.com/en/eu-regulators-approve-biontech-pfizer-covid-vaccine-for-children/a-57697157 **[EXHIBIT LWCF/110 – INQ000469896]**	gov.uk/government/news/the-mhra-concludes-positive-safety-profile-for-pfizerbiontech-vaccine-in-12-to-15-year-olds **[EXHIBIT LWCF/111 – INQ000469897]**	neuro-disabilities, Down's Syndrome, immunosuppression, profound and multiple learning disabilities, severe learning disabilities, or on the learning disability register CV : 3/9/2021 JCVI statement on COVID-19 vaccination of children aged 12 to 15 years: 3 September 2021 - GOV.UK (www.gov.uk) **[EXHIBIT LWCF/36 – INQ000470348]**	w.gov.uk/government/publications/universal-vaccination-of-children-and-young-people-aged-12-to-15-years-against-covid-19/universal-vaccination-of-children-and-young-people-aged-12-to-15-years-against-covid-19 **[EXHIBIT LWCF/65 – INQ000420525]**	**Clinically Vulnerable** Rollout ENG **91 days** MHRA approval and Healthy Rollout ENG **101 days**
5-11 years	2/11/2021 https://www.cdc.gov/mmwr/volumes/70/wr/mm7045e1.htm?s_cid=mm7045e1_w **[EXHIBIT LWCF/112 –**	25/11/2021 https://www.ema.europa.eu/en/news/comirnaty-covid-19-vaccine-ema-recommends-approval-children-aged-5-11 **[EXHIBIT LWCF/113**	22/12/2021 https://www.gov.uk/government/news/uk-regulator-approves-use-of-pfizerbiontech-vaccine-in-5-to-11-year-olds **[EXHIBIT LWCF/85 –**	22/12/2021 Available from 30/1/2022 https://www.gov.uk/government/publications/jcvi-update-on-advice-for-covid-19-vaccination-of-children-and-young-people/jcvi-	16/2/2022 Available from 4/4/2022 https://www.gov.uk/government/publications/jcvi-update-on-advice-for-covid-19-vaccination-of-	MHRA approval and **Clinically Vulnerable** Rollout ENG **39 days** MHRA approval and Healthy Rollout ENG **103 days**

	INQ000469898]	**– INQ000469899]** No EC approval before vaccinations began in Austria and Germany https://www.euronews.com/2021/11/25/eu-medicines-agency-approves-pfizer-s-covid-vaccine-for-5-11-year-olds **[EXHIBIT LWCF/114 – INQ000469900]**	**INQ000420545]**	statement-on-covid-19-vaccination-of-children-and-young-people-22-december-2021 **[EXHIBIT LWCF/54 – INQ000147478]**	children-aged-5-to-11/jcvi-statement-on-vaccination-of-children-aged-5-to-11-years-old **[EXHIBIT LWCF/90 – INQ000257287]**	
6m-4 years	18/6/2022 https://www.cdc.gov/media/releases/2022/s0618-children-vaccine.html **[EXHIBIT LWCF/95 – INQ000420557]**	19/10/2022 https://www.ema.europa.eu/en/news/ema-recommends-approval-comirnaty-spikevax-covid-19-vaccines-children-6-months-age **[EXHIBIT LWCF/94 – INQ000420556]**	6/12/2022 https://www.gov.uk/government/news/pfizerbiontech-covid-19-vaccine-authorised-for-use-in-infants-and-children-aged-6-months-to-4-years **[EXHIBIT LWCF/115 – INQ000469901]**	6/4/2023 https://www.gov.uk/government/news/children-aged-6-months-to-4-years-in-clinical-risk-groups-to-be-offered-covid-19-vaccine-says-jcvi **[EXHIBIT LWCF/116 – INQ000469902]** 12/6/23 COVID-19 vaccination programme:	N/A	MHRA approval and **Clinically Vulnerable** Rollout ENG **188 days**

				Vaccination of 6-month to 4-year-olds in a clinical risk group (england.nhs.uk) **[EXHIBIT LWCF/96 – INQ000420558]**		

Age	Northern Ireland	Scotland	Wales
16-17 years	Healthy 4/8/21 https://www.health-ni.gov.uk/news/first-doses-be-made-available-16-and-17-year-olds **[EXHIBIT LWCF/117 – INQ000383039]**	Healthy 4/8/21 https://www.gov.scot/news/vaccinations-for-16-to-17-year-olds/ **[EXHIBIT LWCF/118 – INQ000469904]**	Healthy 4/8/21 Written Statement: COVID-19 Vaccination – JCVI announcement on vaccinating Children & Young People (4 August 2021) | GOV.WALES **[EXHIBIT LWCF/119 – INQ000469905]**
12-15 years	CEV (withdrawn title 25/8/21) 19/7/21 https://www.health-ni.gov.uk/news/jcvi-updates-vaccination-guidelines **[EXHIBIT LWCF/120 – INQ000383010]** CV 3/9/21 https://www.health-ni.gov.uk/news/health-ministers-four-nations-ask-uk-chief-medical-officers-advise-vaccinating-people-aged-12-15 **[EXHIBIT LWCF/121 – INQ000383071]**	CEV (withdrawn title 25/8/21) 1/8/21 https://www.gov.scot/news/vaccinations-for-young-people-with-certain-conditions/ **[EXHIBIT LWCF/123 – INQ000469909]** CV Cannot locate on gov.scot Healthy 14/9/21 https://www.gov.scot/news/vaccinations-for-12-15-year-olds/	CEV (withdrawn title 25/8/21) 19/7/21 https://www.gov.wales/written-statement-covid-19-vaccination-jcvi-announcement-vaccinating-children-young-people **[EXHIBIT LWCF/79 – INQ000420539]** CV 3/9/21 https://www.gov.wales/written-statement-covid-19-vaccination-jcvi-advice-12-15-year-olds **[EXHIBIT LWCF/124 – INQ000469910]** Healthy

	Healthy 14/9/21 https://www.health-ni.gov.uk/news/young-people-aged-12-15-be-offered-covid-19-vaccine **[EXHIBIT LWCF/122 – INQ000469908]**	**[EXHIBIT LWCF/75 – INQ000420535]**	14/9/21 https://www.gov.wales/written-statement-covid-19-vaccination-jcvi-chief-medical-officers-advice-vaccinating-12-15-year **[EXHIBIT LWCF/80 – INQ000420540]**
5-11 years	CV Cannot locate on-ni.gov.uk Healthy16/2/22 Vaccine to be offered to 5-11 year olds | Department of Health (health-ni.gov.uk) **[EXHIBIT LWCF/125 – INQ000469911]**	CV 18/1/22 https://www.gov.scot/news/vaccinations-for-youngsters-with-specific-medical-conditions/ **[EXHIBIT LWCF/126 – INQ000469912]** Healthy 22/2/22 https://www.gov.scot/news/vaccinations-for-all-five-to-11-year-olds/ **[EXHIBIT LWCF/127 – INQ000469913]**	CV 7/1/22 (as seen on 7/1/22 – the page has since updated) https://web.archive.org/web/20220110185709/https://www.gov.wales/national-protocol-comirnaty-children-5-11-years-covid-19-mrna-vaccine **[EXHIBIT LWCF/128 – INQ000469914]** **Healthy** 20/2/22 https://www.gov.wales/national-protocol-comirnaty-children-5-11-years-covid-19-mrna-vaccine **[EXHIBIT LWCF/129 – INQ000469915]**
6m-4 years	**CV** (as seen) 6/9/23 https://www.nidirect.gov.uk/articles/get-covid-19-vaccination-northern-ireland] **[EXHIBIT LWCF/130 – INQ000469916]**	**CV** 1/9/23 https://www.nhslothian.scot/covid-19/vaccine-hub/vaccines-for-under-5s/#:~:text=NHS%20Scotland%20is%20offering%20the,old%20by%201%20September%202023. **[EXHIBIT LWCF/131 – INQ000469917]**	**CV** ?/9/23 – full date unknown https://phw.nhs.wales/topics/immunisation-and-vaccines/covid-19-vaccination-information/eligibility-for-the-vaccine/ **[EXHIBIT LWCF/132 – INQ000469918]**

h. Public messaging about Covid-19 vaccines

219. CVF is concerned generally about the lack of information provided to people about which vaccination was available, where and when. There were also gaps in the information provided regarding the time it takes for vaccines to become effective and the importance of receiving multiple doses to strengthen the level of protection.

220. In addition, many CVF members were initially unaware that they were eligible for the third primary vaccination and those on an immunosuppressant were given little information as to the best time to take the third primary. Public messaging promoting the vaccine to families and their children was particularly lacking.

D. Formal engagement by CVF with UK government departments, the devolved administrations or other public bodies

221. CVF is / or was a stakeholder in the following NICE appraisals:

> **Antivirals :**
> Casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 [ID4038]
>
> Remdesivir and tixagevimab plus cilgavimab for treating COVID-19 [ID6261]
>
> **Prophylaxis :**
> Tixagevimab plus cilgavimab for preventing COVID-19 [ID6136]
>
> AZD-3152 for preventing COVID-19 [ID6282]

222. CVF has also shared its concerns with UK government informally, for example by way of email correspondence with government departments, applying to start petitions (for example on vaccination of under-18s). The petition we started that "Under 18s must have the option to be vaccinated against Covid-19" was rejected by the Government Petitions Team on the basis that it was not something that the UK government or Parliament is responsible for **[Exhibit LWCF/133 – INQ000469919]**. The content of the petition explained that some children would die without vaccination and that households with CV/CEV members can be at greater risk of mortality even with vaccinations and that vulnerable children urgently needed to be vaccinated and that they and those who live in vulnerable households must be prioritised.

223. CVF has also made a number of Freedom of Information Act requests. On 25 June 2021, we made an FOI request to the Department of Health and Social Care asking the following questions **[Exhibit LWCF/134 – INQ000469920]**:

a. When did the JCVI submit its recommendations regarding the vaccination of 12 to 15-year-olds?
b. What were the recommendations put forward by the JCVI regarding the vaccination of 12 to 15-year-olds against Covid-19?
c. If the JCVI have in fact approved the vaccine for 12 to 15-year-olds why haven't the government accepted their advice/recommendations
d. If the JCVI has approved vaccines for CV and CEV children or households with CV and CEV members, why are less vulnerable 18 year olds receiving their vaccinations before then?

224. The Department of Health and Social Care responded on 23 July 2021, and responded as follows: **[Exhibit LWCF/135 – INQ000469921]**

a. The JCVI submitted its advice regarding the vaccination of 12 to 15-year-olds on 2 July 2021
b. We were directed to the public source and linked to the website and told that the JCVI advised that the following 12 to15-year-olds are offered vaccination – those at risk with severe neuro-disabilities, Down's syndrome, underlying conditions resulting in immunosuppression and those with profound and multiple learning disabilities, severe learning disabilities or who are on the learning disability register as well as 12 to 15-year-olds who are healthy but are household contacts of individuals (adults or children) who are immunosuppressed.
c. The JVCI does not approve vaccinations in the UK the regulator is the Medicines and Healthcare products Regulatory Agency (MHRA) and on 4 June 2021 they MRHA authorised the use of Pfizer/BioNTech vaccine in children aged 12 to 15 years. The JCVI is an independent body made up of scientific and clinical experts that provides advice to the government on use of authorised vaccines at a population level. It has provided specific advice regarding use of the Pfizer/BioNTech vaccine in 12 to 15-year-olds with specific risk factors. On 19 July the government accepted the JCVI's advice and the statement can be found on the website provided.
d. As part of Phase Two of the existing Covid-19 vaccination deployment programme, the Prime Minister set a target of offering a vaccination to all those

aged 18 and above by 19 July 2021. This target has been met. The government accepted JCVI advice on children and young people aged 12-17 on 19 July 2021 and this will now be operationalised as quickly as possible.

225. CVF advocated for the vaccination of CV and CEV children to Rt Hon Nick Gibb. Details on the series of emails are as follows:

226. Our first email, **[Exhibit LWCF/136 – INQ000469922]** dated 26 April 2021, highlighted our urgent concerns regarding the Covid-19 vaccination program for children. Its primary focus was the need to prioritise CEV and CV children for vaccinations. We highlighted the safety of Pfizer and Moderna vaccines and our concerns about the delay in vaccinating children compared to adults.

227. In our follow-up email sent on 7 May 2021 **[Exhibit LWCF/137 – INQ000469923]**, we reiterated the need to prioritise CEV and CV children for vaccination. We addressed concerns about potential recommendations for administering only one vaccine dose to children, advocating that vulnerable children should receive both doses for maximum protection. We also highlighted the challenges faced by CEV children expected to return to school, and the need for clear and consistent guidance to protect these vulnerable groups (CVF acknowledge that these issues will be addressed in a later module).

228. The response from Rt Hon Nick Gibb's office received on 29 July 2021 **[Exhibit LWCF/138 – INQ000474487]** outlined the JCVI's advice, which recommended Covid-19 vaccinations only for specific categories of children over 12 years old. The response indicated that children under 16, even if CEV, were considered at low risk from Covid-19. This response was incredibly concerning to us, as it seemed to overlook both the risk to those children and the broader implications for CV/CEV families.

229. CVF would stress the need for families to have control over health decisions for their children, especially with the risks posed by removing masks in schools and the slow rollout of vaccines for children. The concerns of families with clinically vulnerable and children in CV households have never been fully addressed, particularly as new Covid-19 variants emerge. There is a lack of clear plans for this higher risk population, which might include the option for remote education, to protect these children and families. Over time new variants evolve away from vaccine protection, and so the emergence of a new variants of concern can increase the risks posed to our children and families.

230. For CVF, our concern centres around ensuring the health and safety of CV and CEV children and the protection of children who are household contacts of vulnerable people. We believe that the government's current vaccination policy for children does not adequately address the needs of vulnerable groups to Covid-19.

E. Reports that CVF has published or contributed to, and/or evidence it has given (for example to Parliamentary Select Committees)

231. Our submission to NICE **[Exhibit LWCF/01 INQ000408806]** identified a series of significant challenges faced by severely immunosuppressed people due to the lack of access to prophylactics like Evusheld. To evidence the situation and the ongoing impact of Covid-19, CVF conducted a survey amongst its members to which 350 immunosuppressed households responded. The survey categorised households into "immunosuppressed individuals in immunosuppressed household" and "non-immunosuppressed in immunosuppressed household." The following key issues were raised:

a) **Shielding and Mental Health:** A significant portion of immunosuppressed respondents continue to shield, leading to mental health impacts like anxiety and the need for counselling. 45% of immunosuppressed respondents remained shielding, with 93.6% experiencing anxiety, including 39.7% with significant anxiety.

b) **Masking Practices:** Mask-wearing remains prevalent amongst immunosuppressed households, though less so among children. 89.7% of immunosuppressed adults and 88% of non-immunosuppressed adults in these households reported that they were still masking.

c) **Experiences of Aggression**: Many households reported aggression due to their vulnerable status, especially when wearing masks. 56.3% stated that they faced subtle aggression, 30.9% overt in-person aggression, and 29.1% online aggression.

d) **Impact on Work and Finances:** The survey revealed that being in an immunosuppressed household affects work life, with many feeling unsafe at work or having to give up work, leading to financial losses. 50.2% of households had

one or more adults working from home, and 67.5% felt unsafe at work. Financial loss was reported in 51.7% of households, with 41.6% losing over £10,000.

e) **Educational Impact:** Immunosuppressed households with children faced educational challenges, with many losing schooling days or feeling unsafe in school environments. 81% of households with children reported that they had lost more schooling days than peers, and 88% did not feel safe in schools.

f) **Healthcare Access:** There were issues in accessing healthcare and antivirals, partly due to perceived failings in the NHS's policies and processes and the need for early treatment with antivirals. 61% of immunosuppressed adults had delayed medical appointments due to transmission risks in healthcare and the lack of appropriate infection prevention and control.

g) **Desire for Normalcy and Protection:** There is now a pent-up need by immunosuppressed people to return to their pre-pandemic lives with a restoration of lost freedoms including the ability to travel and engage in normal activities. The lack of prophylactic treatments such as Evusheld via the NHS leaves people at heightened risk.

h) **Perceived Inequity:** CVF contended that the more rigorous approval standards for Evusheld, as opposed to the swifter approval given to vaccines, felt highly discriminatory. The report highlighted a need for equitable treatment in healthcare decision-making.

i) **Potential Impact of Evusheld:** Approval of Evusheld is seen as a way to increase not only protection but also confidence among immunosuppressed people, allowing them to participate more fully in work, education, and social activities.

j) **Unmet Needs and Risks:** CVF believe that the survey clearly identified unmet needs of immunosuppressed people and the risks they continue to face, including the risk of severe Covid-19.

232. Overall, our submission highlighted the need for equitable access to prophylactic treatments like Evusheld for immunosuppressed peoples, emphasising that the lack of such an option had had a significant impact on their lives, mental health, work, education, and social lives.

F. Any lessons CVF considers can be learned or recommendations CVF would wish the Inquiry to consider

233. CVF invites the Inquiry to consider the following recommendations:

a. **Timely Approval and Decision-Making.** CVF understands that delays in the approval of vaccines for children compared to other countries contributed to challenges in the vaccination rollout. We would like to see timely decision making and approvals for vaccines, antivirals and prophylactics.

b. **Logistical Planning and Accessibility.** We recognise that the inaccessibility of doses and variability in local availability, highlight the need for robust logistical planning and distribution strategies, particularly for paediatric vaccinations.

c. **Transparency and Communication.** CVF believes that UK government's approach to vaccine approval and communication around vaccination significantly influenced public confidence and uptake. We advocate for transparency regarding the evidence used for vaccine approval. In the prolonged decision-making process for children's vaccines, a vacuum of uncertainty emerged, allowing disinformation to thrive. Also, when the JCVI focused on a relatively low risk of mild to moderate myocarditis instead of considering the more severe consequences of "inevitable infection," it understandably confused many members of the public. CVF wants to see efforts made to restore public confidence in the benefits of all standard MHRA approved vaccinations.

d. **Learning from Other Countries.** CVF would like to see the UK learning from the approaches of other countries, such as New Zealand and the USA, in promoting vaccines for children. This could provide insights into more effective communication and public health strategies.

e. **Identification of Vaccine Eligibility.** We believe that improved methods to identify and include all eligible individuals, especially those with third-party risk to immunocompromised household members, need to be considered. Once identified, these individuals should be flagged and contacted annually.

f. **Adaptable Systems.** We strongly emphasise the need for adaptability in vaccine distribution systems, as it was evident that significant access issues were

replicated time and again. We believe the challenges faced by different cohorts should have been addressed as the program progressed to ensure the system evolved to meet new and existing demands.

g. **Improved Invitation Systems.** In our view, the NHS must develop invitation systems to ensure that individuals with specific health conditions are promptly and automatically invited for vaccination or for antiviral treatment following a positive test, to minimise distress and confusion.

h. **Addressing Misinformation.** We stress the need for proactive measures to address and counter misinformation. The example of the "shedding" myth emphasises the importance of swift and accurate information dissemination to combat vaccine hesitancy.

i. **Equitable Decision-Making for Children** We advocate for an equitable decision-making process, especially with regard to doses for higher-risk children who had exceptionally long waits for vaccinations which, in our view, were not prioritised in the same way as adult vaccinations had been. Children faced extended waiting periods based on infection history, which then exposed them to further risks as they were not protected during high periods of infection, as adults had been by lockdowns.

j. **Schools Vaccination Programme.** CVF believes that, in line with the UK's approach to influenza, an annual schools vaccination programme should be implemented. This would not only reduce community Covid-19 transmission, improving overall community health, but also reduce school absences and lost learning.

k. **Put Right the Lack of Choice for the Youngest Children to be vaccinated.** All those under 5 in 2022 could not, and have never been able to, access Covid-19 vaccines. This needs to be corrected to give parental choice.

l. **Education and Awareness.** CVF would like to see a strengthening and targeting of public health education and awareness campaigns, emphasising the importance of vaccination and antivirals for those who qualify. Clear and consistent messaging would also enhance public understanding. We recognise the importance of educating clinically vulnerable people, healthcare professionals,

carers, and those in higher-risk groups, who are eligible for antivirals, emphasising the need for rapid access to these vital treatments.

m. **Equitable Vaccine and Antiviral Access.** CVF believes that equitable vaccine and antiviral access could be improved by implementing the following strategies:

i. CVF recommends the need for improved messaging to provide detailed and easily accessible information regarding available vaccines, locations, and booking;

ii. Clear eligibility criteria should be widely publicised for both vaccines and antiviral treatments;

iii. We recommend urgently expanding antiviral access to the broader group, as recommended by NICE, organising pathways for clinically vulnerable people to access treatment rapidly, and we suggest exploring whether a community pharmacy approach could provide a solution to the need for rapid access and distribution issues;

iv. The NHS must also prioritise access to standard treatment pathways for vulnerable patients, ensuring they are not solely dependent on clinical trial participation. Any trial participation, especially by those who are eligible, for a treatment should be based on informed consent about the risks involved in potentially passing up on direct NHS access to that very same treatment;

v. Geographical disparities need addressing to ensure equitable access to vaccination / treatment centres, including planning for better access to specialist treatments, reducing the need for individuals to travel long distances;

vi. CVF supports making antivirals available in advance for high-risk situations such as travel, and allowing private purchase by eligible clinically vulnerable people from pharmacies. This would enable people to more realistically consider holidaying abroad, access medical treatments urgently, and generally improve their ability to access society more. We note that they are available to purchase in other countries such as Australia; and

vii. CVF recommends that the private purchase of vaccines must be made available to all approved age groups (aged 6 months and above).

n. **Safer Healthcare Environments.** CVF would like to see specific consideration for high-risk patients in healthcare, ensuring uncrowded, well mitigated environments.

These should include mandatory mask-wearing, FFP2/3 respirator masks, and enhanced ventilation / air filtration. The upgrades should be across the NHS but priority must be given to areas, such as vaccination hubs, used frequently by higher risk patients. Our members' feedback on drive-through vaccination options was positive as they found it provided a safer alternative to crowded indoor settings. We believe this option should be available more broadly, although we also accept that it is not suitable for everyone.

o. **Planning for Anaphylaxis.** We would like to see consideration given to people with underlying conditions, and the potential interactions between medications to address their concerns related to previous anaphylaxis. Documentation must be available on the NHS website and, where necessary, support offered to those with high-risks who are unvaccinated due to these legitimate concerns.

p. **Equitable Access to Prophylaxis.** CVF emphasises the importance of equity when considering treatments benefiting small subsets of the population, emergency use procedures should have been open to all protective treatments. Prophylactic treatments must hold equal significance to vaccinations in pandemic planning. The significant delays imposed by the government on Evusheld's approval need addressing. We advocate for urgent NHS provision of prophylaxis to Severely Immunocompromised individuals.

q. **MHRA Oversight**. The MHRA must maintain a keen level of oversight of vaccines and therapeutics where the rapid evolution of the circulating pathogens impact on efficacy. CVF are concerned that clinically vulnerable people might have false confidence in outdated vaccines or Evusheld, which is now three generations behind the current Covid-19 vaccines, yet it continues to be sold to patients who remain at extremely high risk.

r. **Healthcare Lottery.** CVF are profoundly concerned over the rise of large-scale long-term trials such as the Panoramic Trial, seemingly positioned as a substitute for standard care practices for individuals widely acknowledged to face substantial risks. The referral of high-risk patients to trial when they are already eligible for treatment via the NHS raises serious ethical questions which need to be urgently addressed.

s. **Approval of Trials.** CVF felt there were serious ethical questions around the Principle trial and that some high risk patients were put at substantial risk. We were particularly concerned that approval was given for a trial which recruited patients up to 15 days post-symptom onset, and the addition of Ivermectin despite substantial evidence against it.

t. **Addressing Inequalities and Disparities.** We, at CVF, are concerned that disparities in vaccine uptake across different groups have highlighted the importance of addressing mistrust and inequality. The 'Community Champions' programme played an important role in disseminating information and addressing concerns within specific hard to reach populations. We wish to see more work done to understand and mitigate disparities in vaccine acceptance within various groups.

u. **Equality Impact Assessments (EIAs).** CVF strongly advocates for the inclusion of being Clinically Vulnerable to infection as a distinct and essential protected characteristic within the Equality Act 2010. We assert that the planning in EIAs lacked due consideration of the substantial impacts on people who fall within the Clinically Vulnerable category. By not directly addressing our needs there was also an absence of community outreach projects which could have fed back of our view, therefore our key issues and specific needs were and are frequently neglected.

v. **Right to Vaccines.** CVF calls for a thorough re-evaluation of the UK's current approach to Covid-19 vaccines. CVF recommend updating the paediatric vaccination schedule to include a standard three-vaccine primary course (as is standard in the US). This would reduce high rates of ICU / HDU admissions seen in this naïve and vulnerable population of under 6-year-olds. Additionally, to address existing inequalities, the government should provide an open-ended offer to all adults and children who have not completed their initial three dose course to do so.

w. **Private Vaccination.** We, at CVF, recommend that Covid-19 vaccines be made available privately, not only to those aged 12 and older but also to younger children and infants aged 6 months and above.

G. Statement of Truth

(1) I, Lara Wong, for and on behalf of CVF, believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Lara Wong for and on behalf of CVF as Founder and Leader

Dated: 04/11/2024

(2) I, Dr Catherine Finnis, for and on behalf of CVF, believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dr Catherine Finnis for and on behalf of CVF as Deputy Leader

Dated: 04/11/2024

ANNEX A

Vaccine Priority Groups and Eligibility[12]

The Joint Committee on Vaccination and Immunisation (JCVI) ranked the eligible groups according to risk. The JCVI advises that the first priorities for the current COVID-19 vaccination programme should be the prevention of COVID-19 mortality and the protection of health and social care staff and systems. Secondary priorities could include vaccination of those at increased risk of hospitalisation and at increased risk of exposure, and to maintain resilience in essential public services[13].

This table sets out the initial JCVI advice on priority groups for primary Covid-19 vaccination.

January 2021 to February 2021	February 2021 – April 2021	Autumn 2021
• Residents in care home for older adults (priority group 1) • Staff working in care homes for older adults (priority group 1) • People aged 80+ (priority group 2) • Frontline health and social care workers (priority group 2) • People aged 75 – 79 (priority group 3) • People aged 70 – 74 (priority group 4)	• People aged 65 – 69 (priority group 5) • People aged 16 – 64 in an at risk group (priority group 6) • People aged 60 – 64 (priority group 7) • People aged 55 – 59 (priority group 8) • People aged 50 – 54 (priority group 9)	• Rest of the adult population (priority group 10)

[12] https://assets.publishing.service.gov.uk/media/650c0d6afbd7bc0014e54715/Greenbook-chapter-14a-4September2023.pdf

[13] https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020/joint-committee-on-vaccination-and-immunisation-advice-on-priority-groups-for-covid-19-vaccination-30-december-2020#vaccine-priority-groups-advice-on-30-december-2020

• Individuals aged 16 – 69 in a high risk group (priority group 4)		

People previously defined as clinically extremely vulnerable (CEV) were considered to be at high risk of severe illness from Covid-10 and these patients were initially flagged on the GP record and advised to shield themselves from exposure to infection. All patients who were on the original CEV list also fell into priority group 6, which included a broader range of disease categories that JCVI advised would constitute a higher clinical risk for Covid-19 vaccinations (tables 3 and 4 of the Covid-19:Green Book, chapter 14a). When the shielding programme ended groups 4 and 6 were formally merged.

In December 2021, following the recognition of pregnancy as a risk factor for severe Covid-19 infection and poor pregnancy outcomes during the Delta wave, pregnancy was added to the clinical risk groups.

In 2021 and 2022, primary vaccination was extended to children and young people aged 5 to 15 years at higher risk from the consequences of Covid-19, including:

- Those aged 5 to 15 years in recognised clinical groups at higher risk of severe Covid-19
- Those aged 5 to 15 years (later restricted to those aged 12 – 15 years) who expect to share living accommodation on most days with individuals of any age who are immunosuppressed.

Primary Immunisation (Dec 2020 -)	Booster (Sep 2021)	Booster (Dec 2021)	Booster (Spring 2022)	Booster (Autum 2022)	Booster (Spring 2023)	Booster (Autum 2023)
• Residents in care home for older adults (priority group 1) • Staff working in care homes for older adults (priority group 1) • People aged 80+ (priority group 2) • Frontline health and social care workers (priority group 2) • People aged 75 – 79 (priority group 3)	• Those living in residential care homes for older adults. • All adults aged 50 years and over. • Frontline health and social care workers. • All those aged 16-49 years with underlying health conditions that put them at higher risk of severe Covid-19. • All carers aged 16	• All adults over 50 years and persons within risk groups. • Those aged 18 – 49 years who were not in at risk groups, in descending age order. • Those aged 16 – 17 years, children and young people aged 12 – 15 who are at higher risk from Covid-19. • Those aged 12 – 15 years who are household contacts of	• Individuals at higher risk of severe Covid-19. • Adults aged 75 years and over. • Residents in a care home for older adults. • Individuals aged 12 years and over who are immunosuppressed.	• Residents in a car home for older adults. • Staff working in care homes for older adults. • Frontline health and social care workers. • All adults aged 50 years and over. • Persons aged 5 to 49 years in a clinical risk groups. • Persons aged 5 to 49 years who are household contacts of people with	• Adults aged 75 years and over. • Residents in a care home for older adults. • Individuals aged 5 years and over who are immunosuppressed.	• Residents and staff working in a care home for older adults. • All adults aged 65 years and over. • Persons aged 6 months to 64 years in a clinical risk group. • Frontline health and social care workers. • Persons aged 12 to 64 years who are household contacts of people with

• People aged 70 – 74 (priority group 4) • Individuals aged 16 – 69 in a high risk group (priority group 4) • People aged 65 – 69 (priority group 5) • People aged 16 – 64 in an at risk group (priority group 6) • People aged 60 – 64 (priority group 7) • People aged 55 – 59 (priority group 8) • People aged 50 –	years and above. • All those aged 16 years and above who are household contacts of immunosuppressed individuals.	immunosuppressed individuals of any age. • Those aged 5 years and over with severe immunosuppression who had not yet received their third dose.		immunosuppression. • Persons aged 16 to 49 years who are carers.		immunosuppression. • Persons aged 16 to 64 years who are carers.

54 (priority group 9) • Rest of the adult population (priority group 10)						

IN THE PUBLIC INQUIRY INTO THE
COVID-19 PANDEMIC

WITNESS STATEMENT OF CLINICALLY VULNERABLE FAMILIES

END OF STATEMENT