All-Party Parliamentary Group on Vulnerable Groups to Pandemics

APPG on Vulnerable Groups to Pandemics

Covid-19 Inquiry Update and Position Statement, March 2023

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Introduction

Since March 2020, the Covid-19 pandemic has imposed widespread challenges for policy-makers, healthcare institutions, public services and the general public. The restrictive effects of the pandemic were once felt by everyone, as the UK entered into a national lockdown to protect the population, and particularly those most vulnerable, from a highly transmissible and potentially dangerous virus on a scale that was truly unprecedented. Nearly two years on, life has largely returned to normal for the vast majority of the public. However, for the most clinically vulnerable, the seemingly distant memories of isolation away from family and friends remain a daily reality. For these groups, the risk to their health remains unacceptably high despite the national return to normality, leaving many of them feeling frustrated, isolated and unprotected.

> *"We are still existing (not living) in this ongoing nightmare. Everyone talks about the pandemic in the past-tense. We are still in it. We can't mix with our families for fear of catching Covid. We can't hug our grandchildren."*
> **-Patient**

According to the Office for National Statistics (ONS), 3.7 million people are classified as 'Clinically Extremely Vulnerable' (CEV) in England, accounting for approximately 7% of the population[1], of which 500,000 were identified by the Joint Committee on Vaccination (JCVI) as having a severely weakened immune system These people are considered at higher risk of serious illness upon contracting Covid-19. This group includes people who are immunosuppressed (due to underlying illness or treatment), people with severe respiratory disease (including cystic fibrosis and COPD) and solid organ transplant recipients. In recognition of the elevated risk associated with Covid-19 infection, CEV individuals were advised by the Department for Health and Social Care and Public Health England (PHE) to shield and follow specific guidance throughout the pandemic[2]. Indeed, protection of the 'most vulnerable' was once at the core of initial public health messaging from the UK government. However, as the focus has moved away from the pandemic, the most clinically vulnerable have been left with a sense of abandonment. In response, the APPG-VPG has agreed to spearhead a national inquiry into the handling of clinically vulnerable groups during the pandemic in order to capture important lessons learned. The *Plan, Prioritise, Protect* report utilised the experiences of patients, charities and other stakeholders in order to formulate detailed recommendations to address current limitations in health policy[3].

In this update, we reiterate the true impact of the pandemic and related policy decisions through a person-centred lens. We invited submissions from those who are classified as clinically vulnerable, friends or family members of those personally affected, charitable organisations, and healthcare professionals. We focus on five key domains relating to health policy:

(i) Availability of, and timely access to protective treatments
(ii) Government decision-making and transparency

[1] Office for National Statistics: Coronavirus and clinically extremely vulnerable people in England: 17 May to 22 May 2021
[2] Appendix A: Timeline of relevant advice/guidance/legislation from *Plan, Prioritise, Protect* report
[3] Plan, Prioritise, Protect: Redefining the needs of vulnerable groups to pandemics through Covid-19 2021 (APPG-VGP/RPP Group)

(iii) Digital and data usage
(iv) Communications with stakeholders
(v) Research and promotion of research activities

Our findings are summarised for each domain, conveying the lived experiences of those most impacted by these decisions.

We would like to thank all those who contributed to this update. Over 450 responses were received. A list of participating individuals and organisations can be found in the acknowledgements.

Key findings

(i) There must be a commitment to equity of protection from Covid-19

- This means providing alternatives treatments if individuals do not gain sufficient benefit from vaccination
- There must be a commitment to a bespoke rapid-access process to ensure new therapies are rapidly assessed and available to patients

(ii) Transparency must be at the centre of government decision-making

- There should be a move away from closed-door committees where people feel their voices are not adequately represented
- Patient involvement is key
- Government ministers and advisors must be willing to answer to public scrutiny

(iii) Data has the potential to empower effective decision-making and inform optimal government strategies in response to pandemics

- There should be an immediate commitment to publish regular metrics, with centralised data programmes designed to assess the effect of the pandemic on vulnerable and immunocompromised patients

(iv) Poor communications have led to significant mistrust in government and health bodies

- Decisions about vulnerable patients must be made in conjunction with patients
- Patient groups should be represented in each scientific and policy meeting and be empowered to feed information back to their communities

(v) The entire strategy of research for immunocompromised groups needs to be re-launched

- Ringfenced funding should be made available to ensure that an ongoing pipeline of new technologies and interventions are made available to people that need them efficiently and effectively

Section I – Availability and timely access to protective treatments

Since the onset of the pandemic, the UK has been an international frontrunner in the search for protective vaccines and treatments. The development of the revolutionary Oxford-Astra-Zeneca vaccine and large-scale rollout of Covid-19 vaccines to the UK population are achievements that deserve praise. Indeed, the rapid rollout and high uptake of Covid-19 vaccines are key factors that have enabled most of us to return to our normal lives, as the risks of getting seriously ill after contracting Covid-19 are significantly reduced in most fully-vaccinated individuals[4].

However, in 2022, research began to emerge that current vaccines were not offering the same level of protection to a large proportion of clinically vulnerable people, particularly those who are immunocompromised. This represents a significant number of the population, as there are approximately 500,000 immunocompromised individuals in the UK. Several studies have shown that vaccine responses are either diminished or absent in patients who are immunocompromised as a result of underlying illness (such as cancer) or treatment they are receiving (for example, steroids and immunosuppressants)[5]. Thus, whilst most people will benefit from Covid-19 vaccination, immunocompromised individuals remain at elevated risk of Covid-19 hospitalisation, intensive care admission and Covid-19 death relative to the general population[6]. This emphasises the need for further protective treatments for those who cannot respond to vaccines.

We invited submissions on availability and timely access to protective treatments for Covid-19 and identified three key themes, which are summarised below. This domain attracted the largest proportion of responses, and forms the largest section in this report to reflect this.

1. Preventative antibody therapies and 'Evusheld' access

Background

The advent of preventative antibody therapies provided many patients with renewed hope of a return to normality after nearly two years of social isolation that has had profound impacts on their mental and physical health. Preventative antibodies are given in addition to vaccines, providing an additional layer of protection if their initial responses to Covid-19 vaccines have been suboptimal. They are given to patients prior to Covid-19 exposure and are particularly useful in people who are unable to produce antibodies themselves (i.e. severely immunocompromised people). 'Evusheld' (Tixagevimab/Cilgavimab) is an example of one of these therapies that made international headlines in 2022 after it was shown to prevent 8 in 10 breakthrough infections in the PROVENT study[7].

On the basis of promising results, the drug was granted regulatory approval in the UK in March 2022 as a potentially viable alternative to vaccination in immunocompromised patients. Later

[4] Agrawal et al. (2022) Severe COVID-19 outcomes after full vaccination of primary schedule and initial boosters: pooled analysis of national prospective cohort studies of 30 million individuals in England, Northern Ireland, Scotland, and Wales. *The Lancet.*
[5] Lee et al. (2022) Efficacy of Covid-19 vaccines in immunocompromised patients: a systematic review and meta-analysis. *BMJ*
[6] Turtle et al. Outcome of COVID-19 in hospitalised immunocompromised patients: analysis of WHO ISARIC CCP-UK prospective study. *(Preprint)*
[7] Levin et al. (2022) PROVENT study for intramuscular Tixagevimab-Cilgavimab (Evusheld) for prevention of Covid-19. *NEJM.*

in 2022, A National Clinical Expert Group of over 125 doctors across 17 specialties, commissioned by the APPG, unanimously agreed that a 2022 Winter plan was of crucial importance for the protection of clinically vulnerable people (including provision of preventative antibody therapies, such as Evusheld)[8]. Despite this, in August 2022, the UK government announced that it would not purchase Evusheld due to "insufficient data on the duration of protection offered in relation to the omicron variant" and based on independent clinical advice given by Rapid C-19, a multiagency group involved in appraisal of Covid-19-related treatments. The drug was then referred for a cost-effectiveness appraisal by the National Institute of Clinical Excellence (NICE), the findings of which have only recently been published in February 2023. Notably, it is the first Covid-19 drug to undergo this intensive, prolonged process prior to commissioning. Furthermore, the level of evidence required for Evusheld to be deemed 'sufficient' was markedly higher than that required by vaccines.

The decision not to purchase the drug was contrary to the verdict given in over 30 other countries. Given the initial UK Medicines and Health Regulatory Agency (MHRA) approval and international support for Evusheld, the discrepancy in judgement between the UK government and the rest of the world has raised legitimate questions from patients, clinicians and parliamentarians. Additionally, in late 2022, Evusheld became available on a private basis, at an estimated cost of £1500-£2000, which has raised further concerns from patients and clinicians about equitable access to the drug.

"I have had to purchase Evusheld at a cost of £2000 for six months [of protection]. I am not a rich person but I want to return to work and see family and friends."
-**Patient**

"The Evusheld procurement process is opaque, and has taken too long."
-**Patient**

Perspectives

The UK government's decision not to purchase Evusheld after preliminary regulatory approval was by far the most commonly raised concern by patients and public supporters. This decision was "devastating" for many who still feel as though their lives are left 'on-hold'. We identified the following key issues raised by patients and their supporters:

1. Lack of transparency from UK government on the decision
2. Decision is contrary to conclusions drawn by over 30 other countries
3. The decision has been construed to be entirely 'cost-based'
4. Private access to the drug is problematic and creates a 'two-tier' system
5. Referral of the drug to NICE has introduced a significant delay to potential access
6. Patients who do not respond to vaccines feel unprotected and undergoing mental health harms.
7. An unblinkered focus on unobtainable 'perfect' trial data is not a reasonable approach in patients who are immunocompromised, especially when there is sufficient real-world data supporting its use

Clinicians, academics and charities have also shared their disappointment with the decision. Dr Lee, academic medical oncologist at the University of Oxford, said: "There is strong evidence emerging across the world that this approach of using prophylactic long-acting

[8] https://www.gov.uk/government/publications/higher-risk-patients-eligible-for-covid-19-treatments-independent-advisory-group-report/defining-the-highest-risk-clinical-subgroups-upon-community-infection-with-sars-cov-2-when-considering-the-use-of-neutralising-monoclonal-antibodies)

antibody therapies in combination with vaccination is an uncontroversial approach to safeguard the most vulnerable patients. The science and data suggest that it would be a successful approach for many cancer and immunocompromised patients at the highest level of risk." Moreover, academics and clinical immunologists have raised concerns around the primary use of in vitro neutralisation data to assess the effectiveness of Evusheld. Clinicians have also indicated that the level of evidence demanded by policy makers to inform their decision (i.e. randomised controlled trials against current variants) is unrealistic given the likely heterogeneity among immunocompromised individuals and the required timescales which will be inevitably outpaced by an evolving virus, both of which preclude the feasibility of running large-scale randomised trials.

Charities such as Blood Cancer UK and Lupus UK have also demonstrated support for prophylactic antibody treatments as protection against Covid-19 for those who are immunocompromised. However, they have warned of the likely decline in effectiveness of Evusheld as newer, more resistant variants emerge. For this reason, there must be a sustained commitment to monitoring the effectiveness of potential protective treatments and decisions about access must be made in a timely manner to ensure that maximum benefit can be achieved.

"I was absolutely devastated to hear that the UK wasn't going to purchase Evusheld after it was approved. Having been forced to shield since the start of the pandemic, this was a shattering blow. I, and my wife, have been condemned to isolate for the foreseeable future."
-**Patient**

Following the recent publication of the cost-effectiveness report by NICE, which has ultimately recommended against procurement of Evusheld on the basis of insufficient clinical evidence, there is concern among patient groups and clinicians that the impetus for developing prophylactic antibody therapies will diminish. Despite this decision, NICE did acknowledge the need for a bespoke rapid access process for drugs such Evusheld, so that any potential newer treatments can be rapidly assessed and made available to the patients who need them most. The APPG are in strong support of this recommendation.

In October 2022, in response to a perceived lack of patient engagement in such matters, CEV groups, clinicians and their supporters orchestrated the national 'Evusheld for the UK'

Image taken from the 'Evusheld for the UK' national campaign.

campaign to raise awareness of the 'forgotten 500K' immunocompromised individuals, many of whom are still shielding due to their excess risk of severe Covid-19 outcomes and perceived lack of protection from the UK government. The campaigners also demanded greater transparency from the government regarding the decision not to purchase Evusheld. The patients felt that "government, self-appointed experts were sitting in closed-door committees, doggedly following a strategy that placed lives at risk, without involving patients or consulting with the wider scientific community." Although the campaign was a media success, and helped to garner interest from parliamentarians, the fight for adequate protection against Covid-19 continues.

2. Access to antiviral therapies

Background

Antiviral therapies have been used for treatment of patients who are already unwell with Covid-19 infection since the start of the pandemic, with varying levels of effectiveness. They remain an important option for CEV groups and those at risk of severe Covid-19. For immunocompromised individuals who are unable to generate vaccine responses, antivirals are the only 'safety net' available to them if they do contract Covid-19. In December 2021, NHS England introduced new "game-changing" antivirals, such as Paxlovid and Molnupiravir. Trials have shown that Paxlovid reduced hospitalisation and deaths by 88%, and former Health Secretary Sajid Javid announced that the UK had secured "more antivirals per head than any other country in Europe", amounting to almost five million doses[9]. By April 2022, NHS England stated that over 32,000 patients had benefited from the new antivirals as out-of-hospital treatment[10].

Perspectives

> *"Due to widespread use of immunosuppressants, corticosteroids and biologic treatments in the management of lupus, as many people in this patient community do not have as much reassurance of protection from the vaccines. The availability of post-exposure treatments has been essential."*
> **-Chief Executive, Lupus UK**

Lupus UK have reported some success with access to post-exposure therapies, including antivirals and have asserted that it has proven essential to their patients. However, our survey respondents raised several concerns regarding access to antiviral treatments. We have summarised these concerns below:

1. Access to antivirals is not guaranteed even if patients are eligible for them
2. Healthcare professionals and agencies including NHS 111 are unclear on the protocol for accessing these treatments
3. The '5-day-window' for antivirals is not always met, with some healthcare professionals not following NHS guidance
4. Patients who have been identified as 'high-risk' have still been denied antivirals
5. Access to antivirals via Covid Medicine Delivery Units (CMDUs) is restricted on weekends, which can lead to delays in accessing potentially vital treatment
6. 'Postcode lottery' with respect to access
7. Concerns about withdrawal of some antivirals from the NHS
8. Lack of certainty regarding protocol for accessing treatment is distressing to patients and their families or carers

[9] Hammond et al. (2022): Oral Nirmatrelvir for High-Risk, Nonhospitalised Adults with Covid-19. *NEJM*
[10] https://www.england.nhs.uk/2022/04/highest-risk-covid-19-patients-receive-brilliant-new-antivirals-at-home/

9. Some patients are unable to take certain antivirals due to contraindications

> *"As clinically vulnerable and immunocompromised, knowing that I will be given priority for treatments should I get Covid-19 has allowed me to stop shielding and return to the office, but I still avoid busy places."*
>
> **-Patient (from Lupus UK)**

The interim clinical commissioning policy relating to antiviral treatments for Covid-19 for the prevention of severe illness states that non-hospitalised patients are eligible for treatment with any of the three antivirals (or Sotrovimab antibody) if:

- LFT or PCR-positive for SARS-CoV-2 infection;
- AND symptomatic and showing no signs of clinical recovery;
- AND the patient is a member of the 'highest risk' group as defined by the Department of Health and Social Care commissioned Independent Advisory Group Report[11,12]

If patients meet these criteria but are unable to access antiviral treatment in a timely manner, this is a significant concern and warrants further investigation and investment to ensure that healthcare providers are aware of, and are adhering to nationally recommended guidelines. Moreover, patients have criticised the existing criteria that states a person must have a positive LFT or PCR test to access antiviral treatment. Some patients report that despite having a clinical presentation strongly suggestive of Covid-19, negative LFT/PCR tests have prevented them from accessing antiviral treatments. A small proportion of these patients also report long-term health complications as a result of repeated Covid-19 infections.

> *"Proposals to limit treatment to paxlovid, a drug with many cautions and interactions considerably worsens the situation. It is indicative of the lack of thought or consideration being given to immunosuppressed people."*
> **-Patient**

> *"My dad was eligible for antivirals when he caught Covid. However, he was assessed over the phone as not needing them as he felt OK at the time. He later died of Covid."*
> **-Patient supporter**

> *"The 5-day window has been a nightmare for patients."*
> **-Patient**

> *"Access to antivirals is patchy, with no easy-to-understand policy. Given that these can be life-saving, this is shockingly negligent."*
> **-Patient supporter**

> *"I was denied antivirals once I contracted Covid when I had been promised them."*
> **-Patient**

3. Booster vaccination programmes

As previously outlined, there is evidence to suggest that some immunocompromised individuals are unable to produce adequate vaccination responses. Despite this, most immunocompromised patients continue to receive their booster vaccinations when

[11] Interim clinical commissioning policy for antivirals in high-risk patients not treated in hospital. DHSC (Jan 2022)

[12] Defining the highest-risk clinical subgroups upon community infection with SARS-CoV-2 when considering use of neutralising monoclonal antibodies and antiviral drugs: Independent Advisory Group Report.

recommended. Many patients expressed concerns about the extended booster vaccination programme specifically targeted toward CEV groups:

1. Some healthcare professionals and agencies (including NHS 111) lack knowledge about who is entitled to receive extra boosters
2. Patients feel as though they are having to “fight” to receive the boosters they need
3. Concerns about the potential futility of continued vaccinations if certain patients have failed to respond in the past
4. Some patients feel unable to weigh up the risks and benefits of continued vaccinations if they know they do not produce adequate responses
5. Vaccination cannot be relied upon as the only method of protection in this group

Although studies suggest inadequate vaccine responses in some immunocompromised individuals, the true implications of this on a person-to-person basis are unclear. This has created distress among many people who feel uncertain about their level of protection despite continuing to receive boosters. CEV groups report a lack of reliable information, advice or reassurance about this particular issue, which has not been directly addressed by NHS or government sources aside from advising that all CEV groups continue to ensure they access boosters. Whilst it is true that vaccination is an important aspect of protection among this group, the uncertainty surrounding the strength and duration of protection afforded by vaccines in immunocompromised groups remains a concern for patients and clinicians. Some patients even report paying for private antibody tests to assess whether they are responding to vaccines or not. Similarly, it is not clear how these tests should be interpreted and there is certainly potential for exploitation by private healthcare providers if this issue remains unaddressed by NHS or government bodies.

Section II – Government decision-making and transparency

The previous *Plan, Prioritise and Protect* report detailed key issues relating to government decision-making, including a lack of patient involvement in informing health policy; a lack of transparency and clarity of policy formulation; mis-categorisation of conditions for those in CEV groups and disagreements with government-defined vaccine prioritisation groups. Several recommendations were made to address these shortcomings. This report summarises further perspectives from patients, clinicians and public supporters regarding government decision-making and transparency.

1. How decisions are made and transparency

The *Plan, Prioritise, Protect* report identified a lack of clarity on rationale and methods of government decision-making as an important issue throughout the pandemic. For instance, CEV people have felt that decisions were often 'ideological', rather than evidence-based. This has been exacerbated by seemingly reactive decisions made by the UK government that did not seem to align with scientific opinion, for instance the decision to mass-discharge patients back to care homes without Covid-19 testing, and reluctance to enforce a national lockdown until insurmountable pressure from advisors had been applied. Although the government has reiterated their reliance on 'world-leading' epidemiology and expert advice from bodies such as the Scientific Advisory Group for Emergencies (SAGE) and the Joint Committee on Vaccination and Immunisation (JCVI), our previous APPG-commissioned report showed that many people were unclear about the role of SAGE, how JCVI guidance and in particular how Rapid C-19 was informed by scientific research. Some clinicians have also raised concerns about a lack of representation of clinical immunologists and those experienced in the longitudinal care of immunocompromised patients at a national decision-making level. Thus, decision-making processes and the organisations or bodies involved should be justified and communicated to the general public in a way that is accessible and transparent. Moreover, lack of patient and charity involvement in decision-making, particularly relating to the 'Living with Covid-19' plan has been widely criticised by patients and charities responding to our survey.

"The attitude that the pandemic is over and that Covid-19 has gone away is very distressing for CEV people."
-Patient

"I feel like I can't trust what the government say."
-**Patient**

2. National lockdown delay

Despite the UK government's initial reluctance to enter into a national lockdown in March 2020, many respondents to our survey felt that a nationwide lockdown was crucial for the protection of those at higher risk of adverse Covid-19 infections, including elderly people and CEV individuals who were placed at the heart of this decision. However, our respondents state that indecision surrounding the debate of lockdown versus 'herd immunity' in the early stages of the pandemic created confusion among the general public with respect to the risks associated with contracting Covid-19 and the level of threat posed by the virus. This also created distress

"We were asked to shield one minute, then abandoned the next."
-Patient

"The government have been too slow to act."
-**Patient**

in CEV groups and their families/friends, many of whom had caring obligations and were uncertain if they could continue to provide care.

3. Care homes

Moreover, hospitals across the UK were instructed to discharge as many patients as possible to generate adequate bed capacity ahead of an unrelenting surge of Covid-19 infections. This was unfolding prior to routine Covid-19 testing in hospitals, and resulted in patients returning to their care homes infected with Covid-19 unbeknownst to them or care staff, putting some of the most vulnerable people in society at alarmingly high risk. This was a monumental, but predictable failure in public health policy that has received considerable backlash from parliament, public health bodies, clinicians and the British media. According to the ONS, over 45,000 care home deaths were attributed to Covid-19 between March 2020 and January 2022 in England and Wales, accounting for 16.7% of all deaths of care home residents[13]. It serves as a grim example of the dire consequences of poorly rationalised, reactive decision-making and will represent a lapse in judgement from politicians and policymakers.

"The removal of all measures for the general public and the onus put on me to protect myself, but with no tools to do so, means I either continue to shield or I return to 'normal' but with a very substantial risk."
-Patient

"The government's indecision and prevarication in the early stages of the pandemic made things confusing for the general public and extremely stressful for me as a patient and carer for my disabled husband."
-Patient and carer

4. Personal protective equipment (PPE) and mask-wearing

The story of PPE shortages and the UK government's mission to meet unprecedented demand is one that continues to evolve. From failure to stockpile appropriate PPE ahead of the first wave of Covid-19, to the lobby-driven procurement of £122m of substandard and effectively unusable PPE from a Conservative peer's company[14], there are a plethora of shortcomings and oversights that inevitably put healthcare staff, key-workers and patients at increased risk during the earlier stages of the pandemic.

"I believe that the government do not care about the CEV at all, we are forgotten and all mitigations that would help us have been removed."
-Patient

After a rapid accumulation of evidence that showed mask-wearing in public places conferred protection against the transmission of Covid-19, there was widespread international agreement that public mask-wearing should form an integral part of public health strategy, particularly in healthcare settings[15]. This was formally adopted in the UK in July 2020, when masks became mandatory in various public settings including supermarkets, hospitals and GP surgeries. This response was welcomed by many CEV people and the wider population as a simple and pragmatic measure to reduce the risk of contracting and spreading Covid-19. However, some respondents felt that the UK government's mandatory mask-wearing

[13] Office for National Statistics: Care home deaths (March 2020 – Jan 2022).
[14] Michelle Mone PPE Scandal (https://www.theguardian.com/uk-news/2022/dec/09/revealed-the-full-inside-story-of-the-michelle-mone-ppe-scandal)
[15] World Health Organisation (2020). Mask use in the context of COVID-19: interim guidance, 1 December 2020

policy ended prematurely and in a context of unmitigated risk to CEV people. Moreover, the lack of encouragement of mask-wearing on public transport and in hospitals has led to a rapid reduction in this health-promoting behaviour, leaving those at highest risk feeling alienated and just as vulnerable as they felt at the start of the pandemic with no choice but to continue shielding. This has also led many patients to avoid healthcare settings, particularly hospitals, where possible as their baseline risk of contracting hospital-acquired infections is already known to be elevated.

5. Covid-19 treatments and vaccine priority

Additionally, decisions relating to the procurement and provision of specific Covid-19 treatments and vaccination have been heavily scrutinised and many CEV people feel that there has been a lack of transparency regarding such decisions. As described in the previous section, the decision not to purchase Evusheld despite prior MHRA authorisation has given our survey respondents reason to believe that decisions regarding treatment access are primarily cost-based, and that the odds are stacked against them because they only account for a 'minority' of the UK population. This emphasises the need to ensure that decision-making processes, specifically relating to treatment access, are fully evidenced and made accessible to the general public and particularly those directly affected in order to build trust in published guidance.

6. A sense of government apathy

A disconcerting theme among many of the responses collected from CEV people and their supporters, was a general sense that they had been 'forgotten' and that this is reflected by the 'pandemic is over' and 'it is just flu' attitude emanating from the UK government. At the start of the pandemic, much emphasis was placed on the importance of protecting the most vulnerable from Covid-19. The emphasis seems to have shifted to a 'learn to live with Covid-19' mindset. But for many CEV people, this is not possible. For instance, some survey respondents report that they have been forced to return to work in environments that place them at what they perceive to be unacceptable risk with no legal workplace protections, while others feel as though they have no option but to discontinue working. Some respondents report that they have not been able to visit family since the start of the pandemic, and many choose not to attend important medical appointments because they no longer feel that hospitals or GP surgeries are safe due to lack of mask-wearing or social-distancing precautions. These holes in public policy, have been damaging for public health messaging and trust in government across the board. What lingers is a sense among communities that there is a lack of regard or support for CEV groups, whom are expected to resume normal life but feel they have not been given the provisions to do so. For instance, many respondents have criticised the lack of financial support or legal workplace protections for those who have felt unable to return to work. Whilst it is recognised that the government faces numerous pressing challenges, continued ignorance of the mental and physical health burdens inflicted

"Quality of evidence the government has based its decisions on is inconsistent with no real explanation why."
-Patient

"Since the relaxing of restrictions, I feel forgotten and a minority, no longer represented, no longer worth investing in."
-Patient

"I will never forget or forgive having this life robbed by an uncaring government."
-Patient

"Decisions were made too late... As a shielder, I felt that we were not always considered."
-Patient

on CEV people by the policy decisions made throughout the pandemic will not serve the government well in the future.

Section III – Digital and data usage

Patient groups and their supporters have raised several concerns regarding the utilisation of digital and data services throughout the pandemic. For instance, the UK government received widespread criticism for delaying the imposition of a national lockdown despite accumulating international evidence showing concerningly rapid transmission of the virus overseas. By March 2020, it was clear that a data-driven response was urgently needed. In the context of a rapidly evolving global public health crisis, where increasing emphasis was placed on the importance of data collection and utilisation to inform evidence-based policy, digital and data usage comprised a crucial part of the UK's response to Covid-19.

1. NHS Digital and the 'shielded patient list'

Between March 2020 and December 2021, the UK Chief Medical Officers (CMOs) outlined and regularly reviewed the underlying clinical conditions for which people should be considered at 'high-risk' of severe Covid-19[16]. These criteria were used by NHS Digital to develop a clinical methodology for selecting patients at high-risk based on coded information in their medical records, enabling targeting of specific advice (including shielding guidance) and information toward these groups and wider healthcare and government services. This ultimately allowed generation of the 'shielded patient list' (SPL) for England, which was disseminated to GPs, hospitals, other NHS services including NHS 111 and government services including the Department for Health & Social Care (DHSC), Gov.Notify and local authorities. GPs and hospitals were also able to contribute to this list if they identified further patients at high-risk. The aim of the SPL was to enable seamless provision of information across different services, allowing for consistent and optimum protection of high-risk individuals. Additionally, the SPL proved to be an invaluable resource for clinical trials and research tools characterising the risks associated with Covid-19 infection in different population groups, including the Q-Covid risk stratification tool[17], and the OPENSAFELY study[18]. Moreover, the list was disseminated to PHE for purposes of vaccine surveillance in CEV groups.

> *"I received a transplant in January 2021, but only after this and vaccine rollout did I find out that I was not identified as CEV. I had to personally pursue a change in classification."*
> **-Patient**

Whilst it is recognised that creation and dissemination of the SPL was a necessary and laudable endeavour to ensure the protection of those at highest risk, patients and their supporters reported many concerns regarding their inclusion on the SPL and its use in practice. For example, several people reported that their CEV status was not always verified

[16] Appendix C: List of underlying conditions considered indicators of extreme vulnerability to coronavirus (set by UK Chief Medical Officers, taken from NHS Digital)
[17] Clift, A et al. Living risk prediction algorithm (QCOVID) for risk of hospital admission and mortality from coronavirus-19 in adults: national derivation and validation cohort study
[18] OPENSAFELY Collaborative: Changes in COVID-19 related mortality across key demographic and clinical subgroups: an observational cohort study using the OpenSAFELY platform on 18 million adults in England

on the list, and many had to push to be added despite meeting CMO-defined criteria. Moreover, some patients reported that they were given contradictory statements from different NHS or government services regarding their eligibility to be on the list, which was a considerable source of distress in the earlier stages of the pandemic. Even once patients were on the SPL, some reported not being given clear explanations as to why they could not access certain treatments or extra booster vaccinations reserved for high-risk individuals. Thus, it is clear that despite its strengths, the data-driven creation of the SPL and its suboptimal utilisation in practice left a sizeable proportion of CEV people feeling unprotected and unvalidated.

The SPL closed following the announcement of the end of the national shielding programme in late 2021, despite the fact that CEV groups are still at high-risk and shielding behaviours continue to this day. Following closure of the SPL, the list is no longer updated with new patients after new diagnoses or changes of circumstance, meaning that although the list is still available to health services and can be considered when providing care, it will not automatically include patients who are newly at risk since the closure of the SPL. This has attracted anxiety among people who have been recently diagnosed with high-risk conditions and are concerned that their vulnerability will be a matter of opinion among healthcare professionals. Furthermore, although the SPL remains available to healthcare and government services, its closure means that it is no longer reflective of the situation in the UK in real-time. The SPL open dataset can be accessed on NHS Digital, and these failures to maintain a data-evidence approach will be reviewed in the national independent COVID-19 inquiry[19].

2. Test and trace (now known as UK Health Security Agency)

Contact tracing, or Test and Trace is a key component of managing outbreaks of disease, and its principles are already routinely used by Public Health England (PHE) for containment of notifiable diseases. Test and trace programmes identify individuals, or groups of individuals, with an infection and trace their recent contacts to provide isolation advice in order to prevent further transmission. In the earliest stages of the pandemic, test uptake was slow and test results were often delayed for several days due to a rapid increase in testing demand. Clearly, the UK's test and trace capacity required considerable expansion in order to obtain efficient and timely test results that could be shared with contacts. In May 2020, the DHSC launched the NHS Test and Trace Service (NHST&T) to and signed several contracts with public and private organisations to provide supplies, services and infrastructure (including the NHS T&T app) to support the programme.

> *"My condition is very rare and most clinicians did not know how to get me on the NHS database despite receiving clinical vulnerability letters. This frustrated my GP and hospital consultants"*
> **-Patient**

Part 1 of the National Independent Covid-19 Inquiry summarises objective limitations of NHST&T, particularly relating to non-compliance, cost-effectiveness, testing capacity and lack of preparation ahead of key public policy changes such as the reopening of schools and workplaces later in 2020[20]. Initial data from the National Audit Office (NAO) showed that despite rapid scale-up of Covid-19 testing, too few test results were delivered within the target timeframe of 24 hours, and too few contacts of infected people were being reached and

[19] NHS Digital Shielded Patient List dataset accessible at NHS Digital
[20] House of Commons Public Accounts Committee (2021): Covid-19 Test, track and trace (part 1). 47th Report of Session 2019-2021

advised to self-isolate from May to October[21]. This generated significant distress among CEV groups, at a time when vaccination and antiviral treatments were not yet available. Over time, testing capacity improved and with the introduction of free government-issued lateral flow tests (LFTs), testing became much more accessible to the general public.

However, in 2022, with the discontinuation of free mass PCR testing and restriction of government-issued LFTs to a small group of people (including CEV people who are eligible for specific Covid-19 treatments), the national trends in Covid-19 transmission are no longer clear. This has left CEV groups feeling unable to accurately assess their risk because the data available no longer reflects the level of Covid-19 transmission among the general population. As a result, many CEV people continue to shield as they are more uncertain than ever about the risks of integrating back into 'normal' life.

[21] National Audit Office (2021): Test and trace in England.

Section IV – Communications with stakeholders

"There is no ongoing communication to update us. Risks may change so we need information so that we can take appropriate steps to adjust how we go about our daily activities."
-Patient

Effective communication regarding the risks associated with Covid-19 infection has been imperative since the start of the pandemic. The UK government achieved this in a variety of ways, including mass delivery of letters notifying those identified as at high-risk, provision of safety guidance tailored to CEV people, and regularly holding national press conferences to provide updated public health guidance based on scientific trends in real time. It was clear from the early stages of the pandemic that the British public must adopt a shared responsibility for the health and safety of those who were at highest risk, as well as for themselves. Whilst these methods of communication were essential and appreciated by the general public, patients and clinicians alike, several criticisms have been raised by respondents to our survey relating to communications with stakeholders during the pandemic. These are listed below:

1. Public health messaging has been confusing or unclear to general public from the start of the pandemic
2. Delays in sending out information to CEV people due to initial confusion regarding who was included in the CEV group
3. Poorly communicated/unclear risks relating to specific conditions such as haematological cancers or those receiving chemotherapy
4. Communication across NHS and government bodies was sometimes poor, leading to inconsistencies in care provided and suboptimal care in some cases
5. Unclear and contradictory messages regarding end of restrictions and shielding
6. Communication with stakeholders has deteriorated over time, leaving many CEV people feeling 'abandoned'
7. Lack of updates or follow-up communications with patients regarding ongoing risks and precautions
8. Slow and inadequate responses from some MPs regarding Evusheld decision
9. Lack of clear communication from government or NHS bodies regarding the issue of suboptimal vaccination responses in immunocompromised, despite this being a key concern among CEV people

"I was missed out from some communications which meant it was harder to access jabs, testing or treatment when I needed it."
-Patient

After criticism regarding a lack of communication with patient groups and charities, the DHSC established the Covid-19 Enhanced Protection Programme Stakeholder Forum in late 2022. This forum enables representatives of patient groups and charities to meet regularly and contribute to public campaigns, and represents a positive step toward more effective communication with stakeholders and patient involvement in matters that directly affect them. Adoption of such a scheme from the outset of the pandemic may have been beneficial for both charities and patients. Although the Covid-19 Enhanced Protection Programme Stakeholder Forum was flagged as being helpful, it was also noted as another 'closed-invite' meeting, not open to the public, and not highlighting all sides of the picture. Independent organisations like 'IndieSAGE' were held up as world-class examples of where government could learn key

lessons in scientific communication focussing on the communication needs of those most affected during the pandemic.

"I've had to use hospital letters and Blood Cancer UK materials to justify my eligibility for vaccinations at both my GP and local vaccination centres who are often behind the latest guidance regarding CEV or immunosuppressed patients."
-Patient

"NHS and government communications regarding the eligibility and timing of most my vaccinations has been variable to poor."
-Patient

Section V – Research and promotion of research activities

The Covid-19 pandemic has placed significant pressure on the NHS, and particularly on clinicians and other healthcare workers who were faced with the challenge of treating and caring for patients infected with a virus for which there was no recommended treatment aside from supportive measures, such as oxygen supplementation and ventilatory support. The UK was a global leader in the search for new treatments and vaccines, and the UK government employed several strategies to facilitate research. Below, we summarise the key themes raised by our survey respondents relating to research and promotion of research activities.

1. Vaccine development and surveillance

As mentioned previously, the large-scale vaccine rollout across the UK was a truly unprecedented feat and was a key driver toward the end of restrictions for most people. To facilitate this process, the UK Medicines and Healthcare products Regulatory Agency (MHRA) were achieved efficient regulatory procedures to enable the rapid development, trialling and licensing of the Oxford-AstraZeneca vaccine as early as late March 2020[22]. From early in the pandemic, it was clear that vaccine development and rollout was an urgent priority for the UK government. This was particularly praised by both CEV groups and clinicians responding to our survey. The general public were assured that real-world surveillance of vaccination safety and effectiveness would be regularly reviewed and scrutinised to identify any safety concerns associated with Covid-19 vaccines. Although there were initial concerns about underrepresentation of effectiveness trials, PHE published a study in July 2021 including data from over one million people in 'at-risk' groups who had received the Oxford-AstraZeneca vaccine[23]. Two doses of vaccine provided around 80% effectiveness against symptomatic disease in risk groups aged 16+ years. Furthermore, vaccine effectiveness was 74% in immunosuppressed people after two doses. This provided some reassurance to CEV groups earlier in the pandemic. However, as new Covid-19 variants continue to emerge and threaten vaccine effectiveness, CEV groups (particularly immunocompromised individuals) are increasingly concerned about the level of protection afforded by vaccines. This has been exacerbated by repeated and ongoing reports of inadequate vaccine responses in people who are immunocompromised. Further surveillance and research into this particular issue is required to provide a clearer answer to both clinicians and patients.

"Accelerating UK vaccine development, including clinical testing, will ensure that any successfully developed vaccine can be made available to people as soon as possible."
-Amanda Solloway
(Previous Science Minister)

"The research effort employed by the scientific and health communities from the start of the pandemic to find a vaccine gave me hope as a person who was at increased risk of being hospitalised."
-Patient

2. New treatments

The efficient MHRA regulatory procedures also facilitated the rapid approval and access to repurposed or new Covid-19 treatments. The international RECOVERY trial, led by researchers at the University of Oxford, compared different available treatments that may be

[22] https://www.gov.uk/government/news/mhra-approves-covid-19-vaccine-trial-in-7-working-days
[23] Whitaker et al. (2021). Pfizer-BioNTech and Oxford AstraZeneca COVID-19 vaccine effectiveness and immune response among individuals in clinical risk groups.

useful for patients with Covid-19 and has enrolled over 48,341 participants worldwide[24]. The UK CMOs disseminated communications encouraging all hospitals in the UK to recruit participants to generate a large and representative sample. Some of the treatments assessed in the trial are now routinely used in the management of patients hospitalised with Covid-19, including dexamethasone and antivirals such as remdesivir. The RECOVERY trial and its promotion by the government and CMOs was praised by many of our survey respondents as an example of promotion of important research to find suitable treatments for Covid-19. However, many CEV people feel that the search for new treatments for Covid-19, particularly for those at high-risk, has dissipated since the earlier stages of the pandemic. With the emergence of new variants, and some CEV people reporting contraindications to currently available antivirals, it is clear that further research for alternative treatments is required. Moreover, both patients and clinicians agree that further investigation into the utility of long acting monoclonal antibodies (such as Evusheld) as pre-exposure preventative therapy is urgently required, especially as social distancing and mask-wearing restrictions have been lifted.

"We support and expedite authorisation of clinical trials for COVID-19 treatments, whilst maintaining our high regulatory standards to ensure the safety of people involved in the trials."
-Dr June Raine
(Chief Executive for the MHRA)

"We seem to be forgotten regarding new research and treatments."
-Patient

Monitoring of risk to CEV groups

It was well-understood from the start of the pandemic that CEV groups were at higher risk of severe Covid-19 outcomes compared to the general population, and this was reiterated by the UK government in the initial safety guidance provided to CEV individuals. Although vaccination has ameliorated the risk of Covid-19 complications in most people, more recent research has shown that CEV groups still remain at excess risk from severe Covid-19 even after recommended booster vaccines,[6,25] indicating that increased protective measures are still required. Aside from continued recommendations for booster vaccination, little has been done to respond to this excess risk or reassure CEV groups. Moreover, the cessation of publication of Covid-19 infection rates has removed the ability for many CEV people to dynamically assess their risk over time. Continued research into the risks of Covid-19 in CEV people are welcomed by patients, clinicians and charities, but the findings must be carefully considered when informing public health policy directed toward CEV groups.

"I don't feel as though I can assess my risk dynamically or accurately."
-Patient

[24] RECOVERY trial – ISRCTN50189673. Recoverytrial.net/results
[25] Lee et al. Third dose booster vaccine effectiveness against breakthrough coronavirus infection, hospitalisations and death in patients with cancer: A population-based study, European Journal of Cancer.

Concluding remarks and recommendations

The findings of this report show that whilst it is recognised that the UK government and policymakers have faced several unprecedented challenges from the onset of the Covid-19 pandemic, numerous lessons can be learned from failures and inadequacies in the prioritisation and protection of CEV people. This report collected evidence from patients, charities and other stakeholders to identify important learning points from these failures and has summarised these in five pre-defined domains.

Firstly, there must be a long-term and enduring commitment to achieving equity of protection from Covid-19 for clinically vulnerable and immunocompromised patients. This requires a greater effort to ensure that people who are eligible for specific treatments, such as post-exposure antivirals, can access them in a convenient and timely manner. There must also be greater appreciation of the cruciality of alternatives to vaccination for people who produce suboptimal responses to currently available vaccines, particularly long acting monoclonals. Furthermore, the APPG strongly advocates for a new rapid-access system for the assessment of new anti-Covid-19 drugs for people who are immunocompromised, as this is an urgent and continuing unmet need.

Secondly, transparency should be at the heart of government decision-making and health policy should be informed by patient experience as well as clinical expertise. Initiatives like the Covid-19 Enhanced Protection Programme Stakeholder Forum represent a step in the right direction, and patient groups and their advocates should feel empowered to provide their perspectives in faith that their voices will be listened to and considered by government when forming new health policy.

Additionally, as digital and data has the potential to bolster effective decision-making and strategy, the government must commit to optimise the infrastructure and systems required to coordinate centralised data programmes to enable the continuous surveillance and assessment of risk to vulnerable and immunocompromised people. This will allow people to undertake dynamic risk assessments when going about their daily lives and will improve the delivery of consistent care and support across different healthcare and government agencies.

Although our respondents have reported some satisfaction with respect to initial communications from government regarding shielding measures, our findings clearly show that there has been an incremental breakdown in communication between the government, health bodies and clinically vulnerable people as time has progressed since March 2020. This has generated significant mistrust in the government and relevant health bodies, with many patients feeling abandoned and ignored. It is imperative that policymakers make decisions in conjunction with patients and stakeholders, and this can only be achieved by an enduring commitment to improving the representation of patient groups and voices in policy meetings concerning issues relating to them.

Finally, despite major successes with the national vaccine rollout and rapid assessment of potential treatments for Covid-19, the impetus for discovering viable alternative treatments for people who are immunocompromised, including antibody therapies and antivirals has diminished. Meanwhile, CEV people and particularly the immunocompromised continue to remain at elevated risk. Ringfenced funding should be secured to ensure that an ongoing pipeline of new technologies and interventions are made available to people who need them efficiently and effectively.

We call on the government to take proactive steps to address these key areas of concern and implore ministers and policymakers to listen to the perspectives of those they claim to serve.

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Appendices

A: Timeline of relevant advice/guidance/legislation (from APPG-VGP *Plan, Prioritise, Protect* report)

Advice/guidance/legislation	**Date**
First Covid-19 guidance	3 March 2020
Guidance for residential care, supported living and home care guidance	13 March 2020
Guidance on social distancing for vulnerable people	16 March 2020
Coronavirus Job Retention Scheme (CJRS) announced (up to 30 June)	20 March 2020
Guidance on shielding for 'extremely vulnerable' people	21 March 2020
First national lockdown measures legally enforced	26 March 2020
Secretary of State for Health and Social Care Matt Hancock announces badge for care home workers	15 April 2020
Communication to adult social care sector of PPE guidance and supply routes	16 April 2020
CJRS goes live	20 April 2020
Conditional lifting of lockdown (allows return to work)	10 May 2020
Announcement that CJRS extended until 31 October (only for employees currently furloughed)	12 May 2020
Changes to legislation on group size and overnight stays, schools reopen, non-essential shops reopen	1, 15 June 2020
Announcement of plans to ease guidance for those shielding	22 June 2020
Relaxation of social distancing	23 June 2020
Lockdown ends, local lockdowns instituted	4 July 2020
Guidance for extremely vulnerable people updated to include information related to the pausing of shielding	31 July 2020
Shielding advice removed, replaced with 'strict social distancing'	1 August 2020
Reduction in generosity of CJRS	August - October 2020
New guidance for young people who are clinically extremely vulnerable and have been shielding	18 August 2020
Return to home working and further restrictions	22 September 2020
Announcement that CJRS extended until 2 December	31 October 2020

Updated guidance for extremely vulnerable people on new national restrictions	4 November 2020
Second national lockdown legally enforced	5 November 2020
Announcement that CJRS extended until Spring 2021	5 November 2020
Second lockdown ends, beginning of 'tiered' restrictions	2, 21 December 2020
JCVI first publish recommendations for vaccine priority groups	3 December 2020
First vaccine received	8 December 2020
Third national lockdown	6 January 2021
Vaccines offered to clinically extremely vulnerable (priority groups 3 and 4)	18 January 2021
Vaccines offered to 'at risk' groups (priority group 6)	15 February 2021
Updated definition of clinically extremely vulnerable groups	16 February 2021
Gradual relaxation of group size, distancing, shop closure requirements following 'roadmap' for lifting lockdown	March-July 2021
Shielding guidance paused	1 April 2021
Guidance updated for clinically extremely vulnerable people to, as a minimum, follow the same guidance as the general population	12 July 2021
Reduction in generosity of CJRS	July-September 2021
Vaccine booster doses administered to vulnerable groups	September 2021
Note to confirm the end of the shielding programme, and to advise that guidance will be updated shortly	14 September 2021
Shielding programme paused	15 September 2021
Guidance updated to reflect the end of the shielding programme	20 September 2021
CJRS ends	30 September 2021
'Plan B' measures introduced, including compulsory facemask wearing	8 December 2021
No significant changes in public health policy have been proposed despite Covid-19 infections continuing to peak and trough (1 in 10 people infected with Covid-19 in July 2022)	2022-Present

B: Vaccine priority groups

Group	Risk group
1	Residents in a care home for older adults and staff working in care homes for older adults
2	All those 80 years of age and over and frontline healthcare and social care workers
3	All those 75 years of age and over
4	All those 70 years of age and over and clinically extremely vulnerable individuals (not including pregnant women and those under 16 years of age)
5	All those 65 years of age and over
6	Adults aged 16-65 years in an at-risk group
7	All those aged 60 yeas of age and over
8	All those aged 55 years of age and over
9	All those 50 years of age and over
10	Rest of population

C: List of underlying conditions considered indicators of extreme vulnerability to coronavirus (set by CMOs, taken from NHS Digital):

- solid organ transplant recipients
- people with severe respiratory conditions including all cystic fibrosis, severe asthma and severe chronic obstructive pulmonary (COPD)
- people with rare diseases and inborn errors of metabolism that significantly increase the risk of infections (such as Severe combined immunodeficiency (SCID), homozygous sickle cell)
- people on immunosuppression therapies sufficient to significantly increase risk of infection
- people who have problems with their spleen, for example have had a splenectomy
- adults with Down's syndrome
- adults on dialysis with kidney impairment (Stage 5 Chronic Kidney Disease)
- women who are pregnant with significant heart disease, congenital or acquired
- people with cancer who are undergoing active chemotherapy
- people with lung cancer who are undergoing radical radiotherapy
- people with cancers of the blood or bone marrow such as leukaemia, lymphoma or myeloma who are at any stage of treatment
- people having immunotherapy or other continuing antibody treatments for cancer
- people having other targeted cancer treatments which can affect the immune system, such as protein kinase inhibitors or PARP inhibitors
- people who have had bone marrow or stem cell transplants in the last 6 months, or who are still taking immunosuppression drugs