Submission in support of sipavibart for preventing COVID-19

– NICE 2024

Dr Penelope Cream, Clinical & Health Psychologist, ACP-UK Director of Operations
p.cream@acpuk.org.uk
Dr Dorothy Frizelle, Honorary Clinical Associate Professor & Head of Adult Psychology Services, St. James's University Hospital; Consultant Clinical Health Psychologist and ACP-UK Director for Strategy & Workforce
d.frizelle@nhs.net

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Executive Summary

Immunocompromised patients and their families are still significantly impacted by shielding precautions to mitigate the risk of severe complications of COVID-19 and, currently, there are few respite options available to those most seriously at risk. In 2023, NICE rejected the use of tixagevimab plus cilgavimab due to insufficient evidence and highlighted the need to understand the mental health impacts on this group when considering prophylactic treatments for these patients. This study examines the psychological and social factors that are known to impact on both physical and mental health using a mixed-methodology approach combining psychological and open-ended questions and is submitted in support of sipavibart for preventing COVID-19. Worryingly, the results showed very high levels of anxiety, depression, loneliness, work restrictions and financial hardship in both the patients and their family members. These results are at a level that would trigger inclusion on NHS England Risk Registers and prompt the provision of urgent psychological assessment and treatment pathways. Recommendations are given, including shared decision making, improved training, the introduction of flagging systems to identify those at risk, the addition of patients to national risk registers, a national government response, enhanced support, including psychological and mental health support and improved medical care.

Introduction

> ***"I am elderly, blind and frail. I am frightened that I might not live to see the day when my daughter has some protection against infection. I want her to be there holding my hand at the end."***

Tixagevimab plus cilgavimab ('tix-cil'; also known as Evusheld) was approved for use in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA) in March 2022 (MHRA, 2022). In February 2023, however, when the National Institute for Health and Care Excellence (NICE) convened to produce guidance for its use, the panel could not recommend tix-cil as more recent studies indicated it was no longer effective against the variants that were then circulating (NICE, 2023). Meanwhile, tix-cil was made available on a private prescription basis only but, to date, has not been provided on the NHS for those most at risk from serious complications of COVID-19. AstraZeneca, meanwhile, went on to develop sipavibart (Evusheld 2; formerly known as AZD 3152), which in the Phase III Supernova trial met its primary endpoints and demonstrated a significant reduction of COVID-19 compared to a control population given tix-cil or placebo, in an immunocompromised patient population (Kemp & AstraZeneca, 2024).

The people most at risk from serious complications of COVID-19 include patients whose primary health condition, or their medical treatments, mean they are severely or significantly immunocompromised, whether as a result of their necessary medications, their medical condition or a combination of these factors and listed in the latest edition of The Green Book (UKHSA, 2024). Many of these individuals do not produce an antibody response to available COVID-19 vaccinations, despite receiving all vaccine rounds to date. This has led to a continued state of shielding or social distancing for them, while the majority of the population has been able to return to normal, post-pandemic life.

Forgotten Lives UK represents these patients. It is a patient support and campaign group founded by Professor Martin Eve, Nikola Brigden and Mark Oakley. Forgotten Lives UK represents the much larger group of 1.3M immunosuppressed and immunocompromised people in the UK who are still leading restricted lives due to their inability to produce protective levels of COVID-19 vaccination antibodies (Barnes et al., 2023). The families of these patients are also significantly affected by restricted activities in order to protect the person who is immunocompromised.

Patients impacted by this continued shielding are unusual in that they come from a very wide range of medical specialties, including oncology, solid organ and stem cell transplantation, immunology, rheumatology, gastroenterology, respiratory medicine, haematology and vascular medicine.

Multiple studies have shown repeatedly (Ohrnberger et al., 2017) that poor physical health and mental health interact to exacerbate health outcomes, health-related and general quality of life, while social isolation and financial difficulties have a significant and detrimental impact on both mental and physical wellbeing. For these families and individuals, these factors need to be investigated together, given the unprecedented impact of the pandemic and their ongoing clinical vulnerability (Dept Health & Social Care, 2023).

It is also important to recognise the negative impact of shielding and social isolation on clinical outcomes, as both lead to poorer mental health. Naylor and his King's Fund colleagues explored this in their seminal 2016 paper, '*Bringing together physical and mental health within primary care: a new frontier for integrated care',* where they emphasise the importance of integrating physical and mental health (Dept Health & Social Care, 2023; Naylor et al., 2016; NHS England, n.d.-b). A recent study by Tian highlights a proposed mechanism of action for the relationship between poor physical health and depression, giving further reasons for the need to support vulnerable patients who may be caught in the vicious cycle of struggling with managing a chronic health condition and mental health challenges (May, 2024; NHS England, n.d.-b; Tian et al., 2024; WHO & Calouste Gulbenkian Foundation, 2021).

A research survey conducted in July 2023 by the Universities of Bath and Liverpool and the All Parliamentary Party Group on Vulnerable Groups to Pandemics found that of the 800 people who responded, approximately 80% were still shielding or significantly isolating (Bernardi & Daniels, 2023). The impact on their mental health, and often that of their close family members, is thought to be considerable. Bernardi and Daniels recommended that further research over time would be important. Daniels and Rettie's 2022 paper found that it is not only the patients themselves who are negatively impacted by living with the continued risk of severe illness and death but their family members too (Daniels & Rettie, 2022). We wanted to further explore the extent of this impact on both groups.

Several charities have been expressing concern about the mental health of the people affected. In October 2023, Versus Arthritis published *Shielding Voices*, a major report on the impact of shielding (Versus Arthritis, 2023).

In 2021, MIND produced *Coronavirus: the consequences for mental health*, a report compiled with information from 12,000 people during the height of the pandemic highlighting the impact on existing mental health conditions (MIND, 2021). For those still isolating or shielding, the challenges of pre-existing difficulties are likely to be ongoing, in addition to continued hypervigilance, avoidance of hospital treatment settings, and isolation. Some may be experiencing traumatic stress following hospitalisation with severe COVID-19.

Often, these patients do not have access to appropriate specialist or even general psychological support, either in the community or via their hospital teams, even though many parts of the UK now offer self-referral via NHS Talking Therapies. However, in the survey presented herein, the authors received reports from several respondents who found that these services did not understand their situations or offered a service that did not meet their needs. The (non-clinician) co-leads of the Forgotten Lives UK group receive heartbreaking stories from patients every week, and single handedly try to manage the desperation and suicidality expressed. This leads to high-risk situations where containment of risk, harm and high levels of distress are falling on lay people while the NHS fails those in severe distress and with expressions of suicidality and, at the same time, places the charity volunteers in risk situations with no back up or support. This is inappropriate and cannot be allowed to continue, and has highlighted a situation that should be added to the NHSE Risk Register as this group of people has significant unmet clinical needs with little or no recourse to appropriate services or treatments (NHS England, 2017b) .

The first NICE guidance to examine the appropriateness of providing tix-cil to NHS patients found that at that time (January 2023) there was not significant evidence that the drug would be effective on the COVID-19 variants then circulating (NICE, 2023). The panel found that further information was needed:

4.3 The committee noted a lack of evidence on how the availability of a preventative treatment would impact on shielding behaviours, to determine the impact on both health-related quality of life and efficacy of treatment. It noted that conducting a survey; similar to that done by the Office for National Statistics, which investigated the proportion of high-risk patients shielding; would be useful.

In response to the panel's recommendation the Association of Clinical Psychologists UK (ACP-UK) in conjunction with the Forgotten Lives UK patient group conducted a survey aimed at collecting data to support or refute the hypotheses that:

1. Continued social isolation negatively affects mental health
2. That mental health and wellbeing of patients' families and loved ones is also negatively impacted
3. Poor mental health indirectly negatively impacts wider clinical outcomes through reduced patient engagement with medical teams.

This survey assesses the impact of continued social isolation on self-reported mental health of both patients and families. It includes both patients and their family members, since it was hypothesised that the ongoing effects are continuing to have a significant impact on both those with the clinical vulnerability and those who live with them or who care about them.

To ensure strong governance around this work, the survey proposal was appraised by ACP-UK's Operational Directors' Group and, following initial approval to progress, further scrutiny was undertaken by the ACP-UK Board of Directors, which is made up of 14 practising clinical psychologists, a director for lived experience and a trainee clinical psychologist. The co-leads of the Forgotten Lives UK patient group worked as partners in developing the survey proposal as well as being involved throughout the process. This survey uses an exploratory format designed to inform a service development, classified by the Medical Research Council as not requiring Ethics Committee approval (Health Research Authority & Medical Research Council, 2022).

The survey aims to examine both patients' and family members' current situations, in terms of their engagement with healthcare services, how they are managing their medical conditions, and their psychological and mental health, the impact of their situations on social interaction, work and finances.

ACP-UK is the professional representative body for clinical psychologists in the UK. It provides an extensive CPD programme for its members, national consultation to major clinical responses and is a NICE stakeholder. ACP-UK sits outside the NHS but holds itself to the same professional, ethical and clinical standards. The majority of its members hold current NHS posts or have held specialist NHS roles previously. It has 10 clinical special interest networks, and an active clinical psychological support service for NHS and social care staff across the UK, and for its members. Many of its members work in medical settings as clinical health psychologists and the organisation is concerned at the potential unmet mental health needs of those who continue to shield or distance socially. Its large clinical team of senior clinical psychologists is well placed and available to provide safe, remote psychological support for these patients and their families and this is recommended in the context of aforementioned risk to patients, families and Forgotten Lives peers should this be possible to arrange.

ACP-UK is not in receipt of any funding for this survey but has acknowledged the unmet clinical need for this patient group, as well as holding concern for the levels of risk experienced by people in continued social isolation. Hence agreement from the ACP-UK Board to support Forgotten Lives UK in their work representing patients across the country and across multiple medical specialties and conditions.

Through analysis of these data, we aim to present a series of recommendations to provide information related to the psychological and mental health impacts of long-term shielding or other significant restrictions experienced by these individuals and those caring for them. This, we hope, can provide an additional perspective alongside the other data presented to NICE for the panel's consideration of sipavibart/Evusheld 2.

Methodology

Participants

Members of the Forgotten Lives UK patient group were invited to take part in a survey looking at the psychological and functional impact on people who remain clinical extremely vulnerable (CEV) to serious COVID-19 complications and hospital admission. A previous study in June 2023 carried out by the group leads indicated that 80% of the 281 respondents were still fully shielding, semi-shielding or socially isolating, and continuing to lead significantly restricted lives compared to their pre-pandemic activities.

Design

The current survey was constructed, conducted and analysed by experienced clinical psychologists with several decades' experience of working in NHS physical health and medical settings as well as in research, across many disease specialties and in both acute and chronic health environments. This allowed for development of questions related to the known key clinical factors impacting CEV people and their families. The survey was piloted with a small group of clinical psychologists, lay people and patients and the link was then shared with the Forgotten Lives UK group via the Facebook platform.

The study survey was distributed for a two-week period between 31 January and 14 February 2024, with a version for patients and a version for family members. An information sheet and point of contact in case of questions was provided for the surveys, and the lead researcher was available to the participants and their families in the case of any queries and in case of any distress as a result of participating in the survey.

The survey used a convergent mixed-methodology approach combining established validated psychological measures widely employed across the NHS and in research settings, and open-ended questions that invited respondents to reply in their own words and share their experiences and reflections. The qualitative data was analysed using a grounded theory approach (Strauss & Corbin, 2024). The survey opened with a single point of entry and information sheet. A branching question identifying if a respondent was a patient or family member then led into the respective questionnaires for each group.

Information related to demographics, main medical condition(s) and lead medical specialty was gathered along with validated measures of levels of anxiety, depression, work and social situation, loneliness, and financial situation, consistent with survey content development. Additional questions enquired about extent of social isolation or shielding behaviours, confidence in managing one's medical condition and interaction with clinical care and vaccination uptake.

Measures

Psychometrically validated and reliable measures were selected for use in the survey. These are used routinely within NHS settings to establish clinical caseness; they also show reliable change following clinical interventions. The measures used for both groups are:

- Patient Health Questionnaire – PHQ-9 (Kroenke et al., 2001)
- Generalised Anxiety Disorder Questionnaire – GAD-7 (Spitzer et al., 2006)
- Work and Social Adjustment Scale (WSAS) (Mundt et al., 2002)
- UCLA Loneliness Scale (Russell et al., 1978)
- Office of National Statistics financial hardship questions (2020) (Financial Conduct Authority, 2023)

The data were analysed using the published clinical cut-off categories for the validated scales, and a thematic analysis was carried out on the free-text responses. The survey was constructed and conducted on ACP-UK's confidential and GDPR-compliant Qualtrics survey platform. The questions could be viewed in their entirety before answering to allow the participants full view of what they were being asked. A format was selected that allowed respondents to answer certain sections and not others, to allow them complete consent in terms of the information they provided. To reflect this the percentages cited in the analyses are for the respondent numbers for each topic or psychological measure.

The mixed-methodology approach was selected to explore information that might not be shared through traditional quantitative questionnaires, and to tap into questions we might not yet know to ask. Open-text qualitative responses allow the participants to share information beyond validated norm measures and provides a rich collection of data that represents patients' and families' lived experiences. This allows an examination of whether the information gleaned is convergent or divergent within the overall data (with convergence indicating a more reliable information set (NIH Office of Behavioral and Social Sciences, 2018).

Open text boxes were provided to explore participants' thoughts on topics including confidence managing their medical condition, attendance at healthcare appointments, access to psychological support, their mental health, and what would help with managing being immunocompromised currently. There was an additional question on the topic of how prophylactic drug availability might affect them, to link specifically to some of the outstanding questions raised by the previous NICE panel about quality of life and impact on behaviour should the medication be approved.

Results

A total of 471 patients and 129 family members responded to the survey, providing both quantitative and qualitative data. A large volume of free text responses was received from both patients and their family members. These comments have been summarised in the themes discussed, and illustrated using selected verbatim quotations. The full data set is available on request.

Respondents

Patients

A total of 471 patients participated in the survey: 76% (n=262) identified as female, 23% (n=78) as male, one person preferred to self-describe their gender (not stated specifically) and three people preferred not to state a gender.

In terms of age, one person was aged 18–24 years, 2% (n=6) were aged 25–34 years, 8% (n=27) 35–44 years, 18% (n=63) 45–54 years. The largest group of 37% (n=126) were aged 55–64 years, 25% (n=87) 65–74 years and 10% (n=34) were aged 75 years or older.

Family members

Of the 129 family member respondents, 67% (n=87) identified as female, 32% (n=41) as male, and one person preferred not to state a gender.

Three family members (2%) were aged 18–24 years, 9% (n=11) 25–34 years, 5% (n=7) 35–44 years, 22% (n=28) 45–54 years, 31% (n=40) were aged 55–64 years, 20% (n=26) 65–74 years, and 11% (n=14) were aged 75 years or older.

Still shielding or socially distancing

Nearly all – 95% – of the patient respondents were still leading restricted or fully shielded lives, with 32% (n=107) fully shielding and 63% (n=217) restricting social activities. Seventeen people (5%) were no longer socially distancing. The majority (93%) of family members were still fully shielding (34%, n=43) or leading a socially restricted life with distancing precautions (59%, n=74), so almost all respondents were still completely or significantly isolating. Nine family members were no longer socially distancing.

Patients' main medical specialties

The patients in this national group are unique. They form a homogenous group through being immunocompromised/suppressed yet are drawn from a very large number of medical specialties, a phenomenon not often seen in medical care. The patients fall under the care of 21 medical specialties, with the largest numbers being treated by haematology, rheumatology, renal and respiratory medicine and transplantation (**Table 1**). The patients reported their lead or main medical specialty providing their care, although not all stated this. It should be noted that it is possible that some come under more than one main specialty, particularly those who have received transplants, whether as solid organ, tissue and/or haematopoietic stem cell transplantation. Some patients, such as those with oncological disease, may experience time-limited immunocompromise depending on their conditions and treatment stages.

We would suggest that this survey sample represents the same proportions of immunocompromised/suppressed patients by specialty across the UK. This raises questions about how best to support the clinicians working in these specialties to look after, provide reassurance and enable psychological care for their patients. Since the patients fall across multiple medical specialties, it is important to recognise that a comprehensive and cohesive approach is needed to obtain a clear sense of clinical need and the impact of isolation/shielding.

Table 1. Spread of patients by medical specialty

Lead medical specialty	Patient numbers (n=403 respondents)
Haematology	97 (24%)
Rheumatology	86 (21%)
Renal Medicine	49 (12%)
Immunology	38 (9%)
Respiratory medicine	28 (6.9%)
Transplantation	21 (5%)
Neurology	14
Gastroenterology	13
Oncology	11
Hepatology	9
Cardiology	8
Primary care	8
Endocrinology	7
Dermatology	4
ENT	3
Urology	2
Ophthalmology	2
Oral medicine	1
Maxillo-facial surgery	1
Infectious diseases	1
Pain management	1

Key Themes

Analysis of the survey data allows us to draw key themes that represent the respondents' situations and experiences of living with immunocompromise at the current time. Results across psychological, behavioural and social measures are summarised in **Table 2**:

Table 2. Psychological, behavioural and social measures

	PATIENTS (%)	FAMILY MEMBERS (%)
Anxiety		
Mild	27	24
Moderate	28.5	32
Moderately severe	20	26.6
Severe	24.5	16.5
	73% in treatment range **44.5% in severe range**	**75% in treatment range** **43% in severe range**
Depression		
Mild	34	37
Minimal	28.4	22
Moderate	17.5	20
Severe	19.8	20
	38% in treatment range	**40% in treatment range**
Work & social activity		
No impairment	8	12
Severe impairment	43	59
Significant functional impairment	48.6	28.9
	91% severely or significantly impaired	**88% severely or significantly impaired**
Loneliness		
Lonely	89.5	94
Not lonely	10.5	6
Avoiding medical appts	48.6	44
Still shielding/distancing		
Yes, fully	32	34
No	5	7
Restricted lives/distancing	63	59
	95% leading restricted lives overall	**93% leading restricted lives overall**
Financial hardship		
Always have difficulty making ends meet	8	9
Sometimes have difficulty making ends meet	21	19
Rarely have difficulty	17	30
Never have problems making ends meet	38	26
Preferred not to say	16	17
	in total 29% report financial difficulties	**in total 28% report financial difficulties**

1 Engagement with healthcare

1.1 Relationships with healthcare professionals
1.2 Confidence in managing health conditions
1.3 Fear and distress when receiving medical care
1.4 Feeling (mis)understood or (un)heard by healthcare professionals

2 Psychological distress

2.1 Anxiety
2.2 Depression
2.3 Loneliness

3 Inability to participate in society

3.1 Work and social activity
3.2 Financial hardship

4 Access to psychological support

4.1 Continued impact of isolation
4.2 Unsafe home situation
4.3 Disrupted relationships
4.4 Impact on children
4.5 Lack of core family contact
4.6 Yearning for a life once lived
4.7 Guilt and fear
4.8 What life remains is limited

1 Engagement with healthcare

1.1 Relationships with healthcare professionals

We were interested in how patients engaged with healthcare provision and self-management behaviours that affect health-related and general quality of life. To explore these issues, we looked at patients' confidence in understanding their health condition as well as their engagement with clinicians and any barriers to remaining as well as possible, whether environmental or personal. Ludman et al. (2013) showed that patients who receive support to care for themselves experience increased self confidence in managing their health conditions, and an improvement in depression scores, even during stressful periods. Conversely, therefore, it is likely that patients who feel unsupported and isolated may find that low mood and physical outcomes deteriorate.

This is a highly engaged group of patients, as shown in their commitment to having COVID-19 vaccinations. We asked about vaccine uptake. The majority of patient respondents (85%, n=291) had received all vaccinations offered. Of those who had not received all or some of the vaccinations, three people (1%) were too unwell, two people had not felt safe enough to enter the vaccination clinic space, 15 people (4%) had had previous adverse effects, which meant they did not have subsequent vaccinations, and four people had been advised by a medical practitioner not to have the vaccination.

1.2 Confidence in managing health conditions

We asked patients, *'How confident do you feel managing your medical condition?'* 344 people responded to this section: 12% (n=41) felt completely confident, 49% (n=169) were somewhat confident, 21% (n=73) were neither confident nor unconfident, 13% (n=46) described themselves as not very confident, and 4% (n= 15) reported being not at all confident.

However, this engagement with healthcare provision and self-management was countered by high levels of distress, fear and anxiety when patients needed to attend a medical setting, as we found when we asked, *'What would help you feel more confident about managing your condition?'*

Many responses were provided, which fall into several main themes. The most frequently cited related to the clinical environment. Patients and their family members describe feeling frightened at having to attend appointments where no one is wearing masks, or at times refusing to wear one when requested by a patient, even in medical settings that treat patients highly vulnerable to infection. There were also multiple requests for HEPA or other ventilation mechanisms in clinical and other settings, such as schools and workplaces.

> *I was confident pre COVID but I now no longer have the support I used to have and regular monitoring I should have. Part of a COVID diagnosis is vaccine challenges – I failed them all, zero antibody response – this won't be different for COVID. If I had prophylactic COVID protection like everyone else in society I would have better confidence to attend healthcare if some mitigations were in place. Without protection and being forced to get sick with COVID that could kill/disable me in the hope that I might get antivirals and they might work in time is unthinkable … Safe healthcare settings and COVID protection would allow me to get my confidence back.*

1.3 Fear and distress when receiving medical care

Both groups described high levels of fear and anxiety when attending medical appointments where masks were not being worn and no mitigations were in place to accommodate their high-risk clinical status. They also expressed anger at the lack of understanding by healthcare staff, and frustration that PPE was not routinely or even occasionally provided in medical specialties where people vulnerable to infection are treated. The stress and fear are described as ongoing, constant and exhausting.

Given the fears related to clinical environments as an infection risk, in particular since infection control measures were largely removed in hospital and clinic settings, we were also interested in whether people felt confident to attend healthcare appointments or were avoiding clinical care. Avoidance of medical care in the context of such significant health conditions could be worsening physical symptoms, lowering or removing levels of support and increasing isolation. All of which lead to worsening mental health as mental health, as previously cited in this report, is associated with all these factors – and all in a patient cohort comprising some of the most CEV patients cared for by hospital teams.

We asked, '*Have you avoided medical appts due to safety fears because of a lack of clinical protection measures?'*
Almost half of the patient group (n=229; 48.6%) reported that they had avoided or continue to avoid medical or clinical appointments entirely or attend only remotely where possible, and 57 (44%) family members reported missing or avoiding medical appointments, out of fear of bringing an infection back into the home. Seven other family respondents reported avoiding them sometimes. This avoidance spans appointments in hospitals, with the GP, with nurses, for blood tests and for screening (including breast and cervical screening and colonoscopy screening tests), and dental appointments and optician visits, as well as with patients' own consultants and specialist healthcare teams.

I had a lump that was growing but avoided going to the GP for over three years as I did not want to risk bringing COVID into our home. At each hospital visit I have been calm about my health but inwardly terrified in case I catch COVID, as despite eight vaccinations my husband has few antibodies worth counting. Always wear FFP3 masks and often surgical gloves under normal gloves. Once home, I strip all my clothes straight into the washing machine and take a shower … My main fear is affecting my husband after 55 years together and married for 52 years. I am his carer and I still love him, so I am scared of harming him. I was not bothered about not celebrating our Golden Wedding, special birthdays, etc, etc, but of my ability to care for and protect him if I had to have chemo, etc, a distance from home with further risks involved.

A core model of medical management in the NHS relies on patients having the ability, largely through self-efficacy encouraged by professional medical support, to manage their conditions safely and effectively most of the time. This is described in the Health Belief Model below (Becker, 1974), which holds as central the theory that patients will undertake an appraisal of the severity of their disease, the perceived benefits of engaging in health-related behaviours and any obstacles to these behaviours. Situations where a lack of trust, perceived low support, a breakdown or endangering of patient-clinician relationships and communication risk poorer physical health, lower levels of engagement and an impoverishment of the care provided and received.

In the circumstances described in this survey and supported by the psychometric measures data, it seems clear that many CEV patients are undertaking a risk assessment of their own safety and finding that the risks outweigh the benefits of receiving optimal clinical care.

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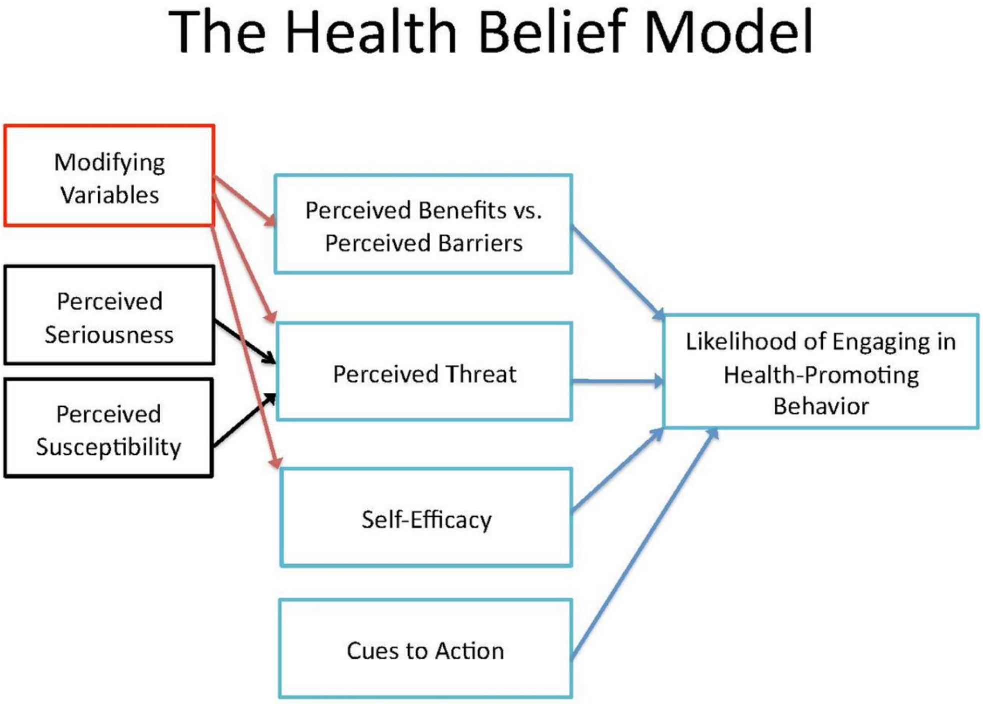

Figure 1: The Health-Belief Model. (Becker, 1974)
Credit: ShareAlike 4.0 International (CC BY-SA 4.0)

I had to visit a specialist eye A&E department as I had an acute symptom that required urgent treatment. The hospital waiting area was so crowded the only safe place the nurses could find for me to wait was out on the street on a busy main road in London. I didn't know if the doctors would even find me there. I had nothing to sit on and it was cold and raining. I was very grateful the nurses understood what it means to be immunosuppressed, but I felt so angry and disappointed that the hospital managers couldn't even allocate a safe space for people in my situation.

I have not seen my immunology consultant since November 2019. I usually see them at least twice per year. I have not seen a dentist for five years. I have not had overdue smear tests. I avoided a needed mammogram for eight months until the worry became overwhelming and I couldn't sleep. I have not attended the GP when required. I was advised two years ago I needed an exploratory gastroscopy and colonoscopy. I have still not attended for this. I am suffering from overwhelming stress, now signed off work and have had no support. I have had booster COVID vaccines on the street as pharmacies have no mitigations in place while inviting CEV to attend.

> *Yes ... all appointments that involve public transport have been via phone. I have had to attend treatments and procedures reliant on FFP3. The hypervigilance and stress are huge and exhausting, and changes in attitudes compound feelings of isolation.*

1.4 Feeling (mis)understood or (un)heard by healthcare professionals

This engagement and self-care were also impacted by a perceived lack of understanding, empathy and practical support from the providing clinicians. There were many reports of people feeling unsafe and insulted when their concerns about being at high risk clinically were minimised or dismissed by the same clinicians or government advisors who only recently had been wearing PPE and providing information about the impact of being immunocompromised during the height of the pandemic.

Respondents wished for better and easier access to their specialist consultants and being able to contact their healthcare teams more quickly. Overall, there was a strong theme of wishing clinicians were more understanding of the patients' and families' situations, and to provide them with more information. They also wanted a more integrated NHS pathway, where NHS organisations worked together to understand their situations, where they received better continuity of care and where doctors communicated more effectively with each other about their care. Some wished for more local healthcare knowledge about being an immunocompromised patient, in particular in GP and primary care settings.

> *Being able to see a medical practitioner safely and not being dismissed as COVID anxious.*

In terms of personal impact, some respondents explained that they would feel more confident managing their condition if they were not living 'under constant threat' and, in particular, if they were taken seriously and not 'dismissed' or their concerns rejected.

> *To feel respected as a competent individual, who is knowledgeable on the issues of COVID, the serious risks it imposes, given my CLL [chronic lymphocytic leukaemia] and its impact on my immunity, and that I'm perfectly rational (not 'fearful', nor 'anxious') for using mitigations for survival.*

Patients and family members alike wrote about their wish for improved public health messaging and more public awareness that there is a large group of people still impacted every day by COVID-19. Some expressed difficulties managing day to day and needed additional sickness and other benefit payments so that they were able to look after themselves more effectively, for example by being able to buy better food.

Some wished for a prophylactic drug against COVID-19, some to know what their COVID-19 antibody levels are, and some asked for psychological support in helping to manage their health condition more confidently.

Greater support – psychological support and greater understanding of the barriers we face.

Being able to have something to help my anxiety levels to go out in the community after four years shielding.

2 Psychological Distress

The validated psychometric measures used in the survey produce stark reading, across both the patient group and their family members. These data were supported by the qualitative comments.

2.1 Anxiety

Patients and their family members both scored highly in terms of clinical levels of anxiety, with 73% (n=222) of patients and 75% (n=83) of family members falling in the range that meets referral for treatment criteria for anxiety. Of particular concern is that 44.5% of patients and 43% of family members fall in the severe range of anxiety symptoms.

2.2 Depression

The scores for depression were also of note, with 38% of patients and 40% of family members scoring in treatment range. In a clinical setting these scores would prompt a referral to a mental health specialist. Twenty percent of both patient and family groups scored in the severely depressed range and would be offered treatment and suicidality risk assessment if in an NHS setting.

My life has been ruined. I feel like I'm in prison; my life has shrunk; I wonder how long we carry on like this.

I have felt desperate and that there is no point to our lives with four of us needing to shield for years. Such severely restricted lives are impacting our mental and physical health as we live in fear.

We would like the government to listen to us. They have just left the immune compromised to rot and die. My partner's metal heath is very bad – he cries constantly. He is 72 and feels life is slipping by. We haven't seen our family in person for four years. My partner has never seen or held his two grandchildren.

Over the past four years, I have seen my bright, intelligent and vibrant daughter turn into a mere shadow of her former self. Her life has been forgotten. She is medically immunosuppressed due to transplant and has had no tangible antibody response to any of her six vaccinations for COVID. Her friends have almost forgotten her and her wider family don't fully understand as much as I do, what the risks and consequences that COVID would have for her. Our relationship was once very close and now it is strained. It is not her fault, but it is not my fault either. We both feel elements of severe cabin fever and cannot believe that we have just been left the way we have … She lives alone and I have feared so much for her mental health. No psychological support has been offered to her, and I think it very much should have been.

2.3 Loneliness

The family members scored even more highly than the patient respondents on the UCLA Loneliness Scale, although both groups reported very high levels of loneliness, with 89.5% of patients and 94% of family members stating they were lonely.

I am now in a care home and am shocked and frustrated that the staff don't understand why my daughter can't visit me. I cry all the time because I'm lonely and they just don't understand.

Our dreams of retirement travelling and taking up hobbies which involve mixing with people indoors are out of the question. My plans to volunteer in hospital and schools are no longer possible and I feel completely isolated. I feel my life is over. This is how I felt when he was diagnosed, but with him responding to treatment I thought we had our lives back only for COVID to take it away again.

Our friends have abandoned us as we no longer can socialise. We would like to go into a shop or a coffee shop or a restaurant or even a holiday. We would stop feeling abandoned and isolated. The bar is very low!

From a clinical perspective, these high levels of significant distress and risk are very concerning in this patient group. High levels of anxiety have been found to be linked to activation of the hypothalamic-pituitary axis, leading to increased sympathetic activation and increased circulating cytokines. These are, in turn, associated with further potential for immunosuppression (Tsigos et al., 2000).

3 Inability to participate in society

3.1 Work and social activity

The WSAS is a brief, validated 5-item scale that measures the impact of mental health difficulties on everyday functioning across work, home management, social and leisure activities, and personal and family interactions. The scores for both patients and family members are of concern, with 91% and 88% respectively severely or significantly impaired. These scores suggest that for both groups their mental health states are severely impacting on their day-to-day functioning across several core domains of everyday life.

[Our son] is currently unable to work, not just due to this immunosuppression, but because the last four years of shielding have had a severe impact on his mental and physical health, and he also has severe clinical depression with no psychological support from the NHS.

I have become a ghost, an invisible person. I want to get back to society and participate again. I want to earn. I want to help people. I want to belong. I want to relate.

3.2 Financial hardship

In total, 29% of the patient respondents and 28% of their family members reported living with financial hardship. It should be noted that this question elicited a substantial number – 16% and 17% of all who responded to this question – declining to answer. We cannot know the reason for this without further research, but we also cannot discount the fact that living in poverty remains a source of stigma and shame for many people and that some respondents may have wished to keep personal financial hardship a private matter.

I have been working from home but work is starting to lose patience and I expect that I am going to lose my job before long. I was hoping that I would be able to get a new fully remote job but those positions are disappearing or very badly paid. I have been in my current job for 24 years and it would be sad to go.

My husband is the breadwinner and self employed, we can't afford to live if something happened to him.

This theme is important from a health inequalities perspective as well as highlighting the significant mental health impact. People living with financial hardship have poorer outcomes for clinical conditions (Fell & Hewstone, 2015). Those who are isolated for clinical reasons are also being prevented from participating in society, which in turn worsens poverty and earning potential. It follows that vulnerable people are being made more vulnerable due to an inability to access treatment, which in turn could alleviate perceived threat and so impact health behaviours. Vulnerable people find themselves caught in a vicious circle in which they are becoming increasingly at risk of poor and unsafe outcomes.

There has been no mental health support offered. We are forgotten and have simply been left to 'get on with it'. There's no support and very little understanding.

There's a lack of support systems in place for those who need it and even if people can get onto lists, the waits are extreme.

Just someone listening and understanding our situation would make a big difference. At the moment, we are either hidden or made to feel we are overreacting.

Even though I have not sought psychological support myself, I am suffering from clinical depression as a result of myself and my wife having to severely restrict our lives over the last four years to protect our 39-year-old son who lives with us and cannot support himself. I have been prescribed antidepressants to help me to cope with this situation, but the tablets I take are not helping. The mental health needs of carers of people who are immunosuppressed also need to be recognised.

4 Access to psychological support

Given the severe levels of psychological and functional and social impairment reported we were interested to examine the data gathered about access to and use of psychological support.

We asked if the respondents had considered accessing psychological support since March 2020. Of the 309 patients who responded to this section, 39% (n=123) had considered seeking psychological help, and 48% (n=149) had not. Another 6% (n =19) had wanted to access support but it had not been available to them, and 5.8% (n=18) said they would have liked to access psychological support but it was only available privately and was too expensive for them to access.

Of the 127 family members who responded to this section of the questionnaire, 31% (n=40) had considered seeking psychological help, and 48% (n=61) had not. Another 3% (n=4) had wanted access but it was not available, and 9% (n=12) respondents said they would have liked to access psychological support but it was only available privately and was too expensive.

The picture appeared to vary depending on where people were located, local provision and the availability of specialist services within medical teams. Some people described how helpful mental health input had been for them, and others chose to give more details about their wish for psychological support.

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4.1 Continued impact of isolation

The respondents were aware that the survey was in the context of a review of Evusheld 2 (as it is known amongst this cohort). The previous NICE appraisal feedback on tix-cil expressed a wish for more detail about the personal impact on individuals, so we asked the survey participants what would help them manage and if they wished to share anything else about the impact their situations are having on their lives currently.

There was a very high response rate to these questions. We have selected excerpts from some of the many themes that emerged from the information shared to allow the participants to explain in their own words:

4.2 Unsafe home situation

Some respondents described challenging or unsafe home circumstances, including living in an environment of domestic abuse or with an alcoholic partner, or as a full-time carer with no respite:

> *Being able to have some time to myself instead of full-time carer with no assistance.*

> *It would change my life beyond recognition. I have to do everything alone as it stands. I need my daughter please.*

4.3 Disrupted relationships

People wrote about lost friendships, family tensions, troubled and stressed marital relationships. They described a sense of detachment from the outside world and from other people whose lives had moved on.

> *My relationship with my husband has suffered greatly over these few years. It's awful.*

> *Sometimes it feels as if the only way to get my life back is to leave my partner.*

4.4 Impact on children

People described children not being able to take part in the same activities as their friends, such as swimming, family outings, seeing their grandparents and having holidays. Parents talked about their children not having the experience of being able to know what it is like to go on outings with their father.

4.5 Lack of core family contact

> *Just to be able to see Mum and Dad would be amazing – we miss them so much and the grandchildren have missed precious time with them. So anything that would give them a bit of confidence to be a family again would be wonderful.*

> *I would be able to hug my daughter-in-law, son, granddaughters, and great grandchildren.*

She would be able to visit me and give me a cuddle. She would be able to take me to her house to see my granddaughter and great grandchildren.

4.6 Yearning for a life once lived

There was a strong longing not for adventure, excess or luxury, but for normal, everyday activities, such as playing a sport, singing in a choir, attending faith-related or religious events, having a coffee inside a café, meeting friends, going to a shop and hugging grandchildren.

It would change our lives enormously. We would be able to live a normal life – that is all we ask. We just want our lives back.

Give me my life back.

For my wife to receive Evusheld 2 would give her back life again – since shielding she is a shell of herself from the person she once was, and the woman I married. Our whole world has shrunk to just existing within four walls – and has had an huge impact on both ourselves and our children.

Our mental health would improve tenfold. She would be able to live again. We could go inside places together and do all the things we have missed. It would be our so-called Freedom Day.

4.7 Guilt and fear

A sense of intense fear and guilt was expressed by family members who lived constantly with the anxiety of being the potential cause of infection and death of their loved ones.

The difference to my partner not feeling guilty that he is causing us to lead a restricted life. My kids would be able to participate in activities inside with their dad. They would love to go to cinema or trampoline park with their dad.

I would be devastated if I infected her.

> *It would give all our family our life back and we wouldn't live in fear of making my father gravely ill or worse. It's bad enough that we live with his health condition.*

> *If I infected him and he was hospitalised because he is immunosuppressed, I would feel very guilty. If he had Evusheld 2 I would feel we had done everything we could to protect him.*

4.8 What life remains is limited

Many of these patients and their families already know that they are living with terminal or life-limiting conditions, which would have been difficult enough without the additional impact of COVID-19 and CEV status.

The respondents described the 'heartbreaking' impact of losing years in isolation when they are already aware their lives are limited, of a loss of social contact and work, and not being able to spend time with friends and family.

> *At 79 years old COVID has already taken away some of my valuable later years. Anything to help me enjoy my life from now onwards would be appreciated.*

> *It took me two full years to mount a response to eight COVID vaccinations … due to this I lost my livelihood and my precious remission years. What a waste of valuable living years. Sad that after 32 years of work life it was cut short when prophylactic help was available for over 30 other countries.*

Discussion

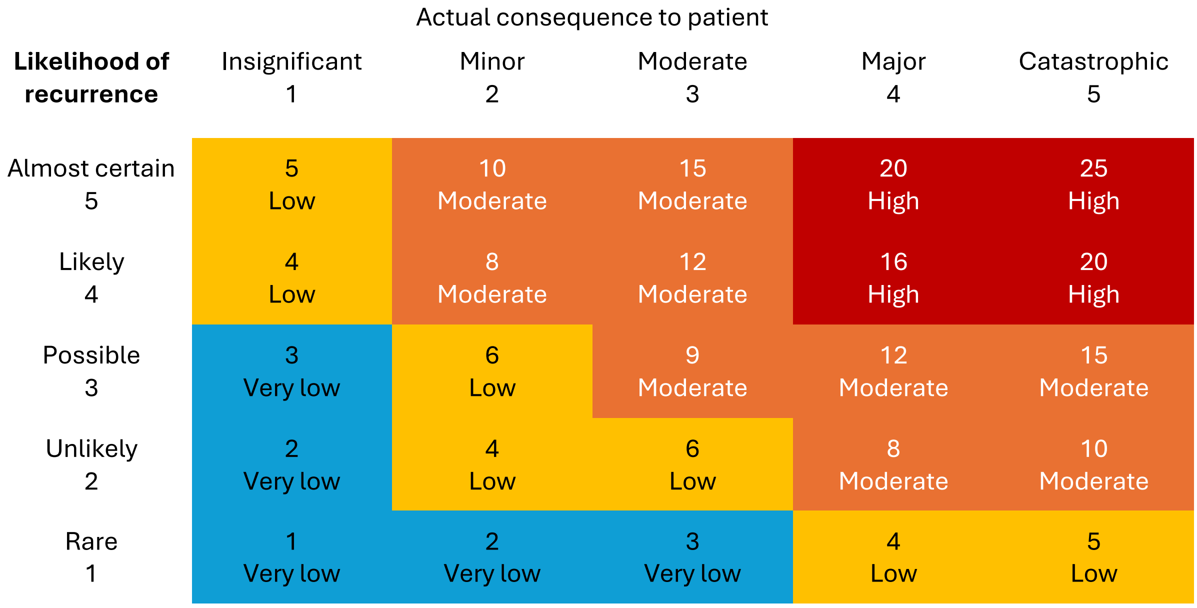
This is a very engaged cohort of patients and family members who prioritise their own and others' safety and who follow medical advice carefully. They demonstrate high levels of self-efficacy and motivation and want to lead full and fulfilling lives. Instead, not feeling **safe** enough to receive care and undertake self-care is the barrier to maintaining as good physical and mental health as possible. This is compounded by a lack of infection mitigation measures in hospitals, a lack of specialist and general psychological support, of healthcare staff and public knowledge, and available prophylaxis for COVID-19 infection.

Our results are very concerning: it is unusual for a participant group – especially across so many different medical conditions – to report such high levels of depression, anxiety, loneliness and impacted work and social functioning. This study finds that the striking levels of distress reported in previous research appear to be persisting and increasing the longer the immunocompromised cohorts of patients and their families continue to shield or remain isolated socially (Bernardi & Daniels, 2023; Daniels & Rettie, 2022; MIND, 2021; Versus Arthritis, 2023). The strong convergence between the psychometric measures and the qualitative data provided by the survey respondents across the large sample size allows us to consider the data as presenting a reliable picture at this time (NIH Office of Behavioral and Social Sciences, 2018).

How long will this situation continue? It seems likely that people will die and families continue to be impacted if no additional mitigations are provided in this country. The psychological harm in these groups is very high and must be included within cost–benefit analysis. The NHS now records psychological harm alongside physical harm in relation to patient incidents. Using the NHS risk matrix (**Figure 2**) to assess the ongoing risk to mental health, the risk rating for this group is very high and corresponds to a score of 20, or 'major' level of risk as there is currently very little likelihood of change for those experiencing severe or very high levels of mental health difficulty related to their isolated situations. A score of 20 indicates immediate mitigating action is required – and would be implemented in NHS settings where these scores are found.

Social and psychological functioning

Both groups of participants in this survey report high levels of anxiety, depression, loneliness, impaired work and social functioning and some financial hardship. Depression is linked to the disruption of work, social and leisure functioning; although we have not attempted to examine a correlation within this survey design, it is highly likely that disruption of social functioning, work and reliable income have a bearing on low mood and depression. Research has shown on many occasions and across many medical domains that depression is linked to an increase in physical health presentations and a worsening of existing long-term conditions (Health [UK], 2010). A reciprocal relationship between physical health outcomes and mood has been found repeatedly (Ohrnberger et al., 2017). Co-existing mental and physical health difficulties are highlighted by NHS England (2018) with treatment pathways and recommendations, and special mention of the need for treatment and medication in patients with long-term physical health conditions. However, as we can see from these data, the mental health of the immunocompromised shielding or socially distancing patients is not being assessed routinely and no consistent provision has been put in place to provide appropriate, specialist psychological support.



	Actual consequence to patient				
Likelihood of recurrence	Insignificant 1	Minor 2	Moderate 3	Major 4	Catastrophic 5
Almost certain 5	5 Low	10 Moderate	15 Moderate	20 High	25 High
Likely 4	4 Low	8 Moderate	12 Moderate	16 High	20 High
Possible 3	3 Very low	6 Low	9 Moderate	12 Moderate	15 Moderate
Unlikely 2	2 Very low	4 Low	6 Low	8 Moderate	10 Moderate
Rare 1	1 Very low	2 Very low	3 Very low	4 Low	5 Low

Figure 2. Adapted risk matrix. A Datix incident report must be completed for every event, regardless of score. (NHS England, 2024a)
Adapted from Leeds Teaching Hospitals NHS Trust's Risk Matrix for Incident Grading 2016 and Worcester Health Authority's Sentinel Incident Reporting System, 2015

A wish to work

The participants in this study express a wish to work, return to work or continue to work and engage in activities that are meaningful to them. For the NHS to support them in engaging with society and the economy would be in keeping with the government's initiatives to help people back to work and to reduce the costs of lost output due to illness. There are 8.65 million people currently economically inactive, with the most common reason for this being long-term sickness (Evans & ONS, 2024). Many immunocompromised people are capable of working if the environment is safe enough for them to do so, and work and the social and economic advantages that come with this are known to benefit mental health (WHO, 2024).

Loneliness

The worrying levels of loneliness reported here must be taken seriously. Loneliness, social isolation and lack of social relationships have been shown repeatedly to impact adversely on health. Loneliness has been shown to correlate with detrimental effects on the immune system (Pourriyahi et al., 2021), coronary heart disease (Valtorta et al., 2016), cognitive functioning and frailty, particularly in the older population (Gale et al., 2018; Luchetti et al., 2020), adherence to medical treatment (DiMatteo, 2004) and overall healthcare costs (Meisters et al., 2021). Here we have a potentially large section of the UK population already living with complex health conditions and in a state of enforced loneliness, with currently little respite available to them.

Brooks and colleagues found that the longer people are isolated or quarantined from others the greater the psychological impact, financial burden, perceived and experienced stigma and the greater the health anxiety experienced. They suggest keeping quarantine periods as short as possible (Brooks et al., 2020).

Daniels & Rettie's 2022 paper highlighted the importance of looking at the mental health impact of shielding in both the immunocompromised as well as in those keeping them shielded. Families, including young people and children, have been profoundly impacted by the precautions taken to keep the patient safe. Our survey results show that those shielding others are equally vulnerable – if not more so on certain domains – to significant psychological difficulties and mental illness as a result of the continued situation. They also experience extreme loneliness, financial hardship, and loss of work roles, with the additional burden of the fear and guilt of living with the possibility that they could bring severe illness or death to their immunocompromised family member.

Financial hardship

To enquire about financial hardship we used questions similar to some used in the Office of National Statistics *Financial Lives Survey* (2020) as this remains a highly relevant document to this group of patients and their families (*Financial Lives 2020 Survey: The Impact of Coronavirus*, 2020). People who are still leading significantly restricted socially distanced lives are in many cases in similar situations to the general population's during the height of the pandemic and lockdown phases. The Financial Lives Survey highlights the particular impact of the pandemic on those of working age, which is also reflected in the family members' and patients' responses here. There are descriptions of losing employment, a fear of losing income and/or restricted expenditure, and of facing the loss of long-held jobs as the rest of the workplace returns to face-to-face working, which they cannot join.

The Financial Conduct Authority describes in the Financial Lives Survey conditions that define vulnerability as:

- *Health: health conditions or illnesses that affect the ability to carry out day-to-day tasks*
- *Life events: life events such as bereavement, job loss or relationship breakdown*
- *Resilience: low ability to withstand financial or emotional shocks*
- *Capability: low knowledge of financial matters or low confidence in managing money, and low capability in other relevant areas such as literacy or digital skills*

Immunocompromised patients and their families seem likely to fulfil some if not most of these criteria, especially if they have experienced the acute onset of their health condition or significant traumatic life events prior to or during the years since March 2020. It should be noted that many health conditions begin as traumatic events, whether through devastating life-changing diagnoses, difficult and frightening treatment experiences in hospital, ongoing complications, bodily disfigurement, urgent care needs and bereavements. Family members are also significantly impacted by the experiences of the patients, and experience acute and post-traumatic stress conditions themselves, and at times more so than the patients.

Recommendations

Protecting, supporting and empowering this group of patients is essential. Patients regularly report that they want to be more involved in their care, and where patients are empowered, they are able to discuss the benefits and risks of treatment options and consider how these align with their personal goals, before reaching a shared decision about their treatment and future care. This is in line with the recommendations of the long-term conditions report *The*

Forgotten Majority? and the Personalised Care Operating Model (Future Health, 2023; NHS England, 2021c).

In many cases, the patient is best placed to manage their condition(s) and can also lead their own recovery and rehabilitation with support. Empowering patients to make decisions about their care can also have wider benefits to them, their families, unpaid carers and communities (Head et al., 2021).

Healthcare systems will need to move away from a single condition approach and care will move to co-ordination across primary, secondary and community care. The Major Conditions Strategy (Dept Health & Social Care, 2023) advocates secondary prevention through intervening early to reduce exacerbations and complications. This has risen to prominence following the COVID-19 pandemic, where it is likely that millions of people did not come forward as usual for check-ups, tests, scans and treatments (Gardner et al., 2020). This strategic framework identifies and delivers several specific actions to be taken now, recognising the very present and significant health risks that derive from low uptake of secondary prevention. Sipivabart could provide this secondary prevention, and to a cohort of patients that is highly motivated to receive it.

Clinical care across medical specialties

In addition to the individual medical care needs of these patients, there is an urgent need to address their common vulnerability across all specialties. Since they fall across multiple medical specialties, it is harder to get a clear sense of clinical need and the impact of isolation/shielding, yet they all hold these characteristics. We would strongly recommend that this patient group is considered in its entirety and collated across specialties. This cohort makes up a large number of people, who need to be considered within risk–benefit ratios and an assessment of impact against cost.

These patients need to be added to the NHS England Risk Register ((NHS England, 2017a), and with support provided to the medical teams looking after immunocompromised patients to enable them to provide consistent and clear support focused on a model of care that pivots around whole-person care.

We concur with, and reinforce, the recommendations offered by Bernardi & Daniels, 2023. Their recommendations were made based on data gathered some time ago. However, our survey results show that these cohorts continue to experience the same difficulties, and to a greater degree in many cases.

Their recommendation: *Recommendation II 2. The Government and DHSC need to formally recognise and respond to the psychological impact of shielding during the pandemic, including the ongoing psychological needs of those who are shielding. Ring-fenced funding should be provided to NHS trust with accompanying mandatory guidance around the provision of psychological care for those who are shielding themselves or others. This would take the form of evidence-based psychological support in an accessible and inclusive format.*

and
Government and health bodies that advise must increase preventative and early pharmacological interventions for those who are clinically extremely vulnerable. The implementation of changes to current regulatory assessment systems and implementation

procedures to ensure any new COVID-19 drugs are made available as a priority and rolled out fast pace across all cohorts to ensure that the unmet need of immunocompromised patients is met at speed. Delay and uncertainty only compounds insecurity and is further detrimental to the mental health of and wellbeing of all those affected.

and

Government and all relevant departments must work to ensure meaningful patient engagement is put in place to ensure that the experience and needs of patients are fully incorporated in any new policies or systems implemented.

We welcome NICE's previous observation in 2023 that there was a lack of evidence of how a preventative treatment would impact on shielding behaviours and the impact that it might have on both health-related quality of life and efficacy of treatment, and its call for a survey:

4.3 The committee noted a lack of evidence on how the availability of a preventative treatment would impact on shielding behaviours, to determine the impact on both health-related quality of life and efficacy of treatment. It noted that conducting a survey; similar to that done by the Office for National Statistics, which investigated the proportion of high-risk patients shielding; would be useful. (NICE, 2023)

We have done exactly that and have ourselves been shocked by the severity of the clinical needs and detrimental impact on so many social, psychological and mental health domains. These should not, and cannot, be ignored; their severity calls for immediate assistance to be provided for these patients and their families. Risk factors often cluster, further driving the increase in experience of multiple conditions and health disparities therefore must be addressed.

We strongly recommend that vulnerable patients are provided with a degree of protection that will impact perceived self-efficacy, choices and behaviours in favour of a richer quality of life. In turn, these factors and choices will lead to improved mental and physical health outcomes.

Vaccination uptake

The present study demonstrates high uptake amongst the respondents, but we acknowledge that we did not ask about ethnicity or geographical location and are aware that certain medical conditions disproportionately affect those from particular ethnic or minoritised groups who may be under-represented in the Forgotten Lives UK group, and potentially in the charities and patient groups that represent immunocompromised people. A recent study (Chen et al., 2024) found that there continues to be poorer uptake of COVID-19 vaccinations amongst certain groups of patients. Any outcomes of this next NICE guidance should make strenuous efforts to reach and include those patients and their families, as should any provision of psychological interventions and support.

Improved support

In keeping with our findings in mental health, healthcare engagement, self efficacy and financial and working lives we strongly support the recommendations made in the Versus Arthritis *Shielding Voices* report regarding improved information provision, (un)employment support, access to essential health services, taking note of unmet needs, and addressing mental health needs resulting from the pandemic (Versus Arthritis, 2023). The Versus Arthritis research was completed between October 2021 and January 2022. Our research has similar findings two years on and takes into account the continuing effects and ongoing impact of entering a fifth year of shielding or distancing precautions for many.

Versus Arthritis' recommendations that we encourage healthcare providers to put in place include:

Mitigating the consequences of shielding:

1. The Department for Work and Pensions should ensure that there is employment protection and enforceable access to workplace adjustments for immunocompromised or immunosuppressed people, including the duty to consider working from home wherever possible.

2. NHS bodies across the UK need to make greater provisions to ensure that people required to shield can access the essential health services they require. This includes an in-person offer, as well as online support.

3. Future mental health plans released by government health departments across the UK need to address the mental health needs of people who were required to shield, with funding allocated to support those with unmet needs resulting from the pandemic.

4. People who are advised to shield should receive clear information and guidance, along with a written record of this advice that they can use to show to employers and others.

Although psychological services are available in primary care across the UK these are often only provided at Levels 2 and 3 while many of the patients in the CEV groups have complex and multiple difficulties that need to be addressed by those with Level 4 expertise. It is important to recognise that these patients often live with multiple morbidities yet are cared for within a system that does not always meet the needs of complex co-morbid presentations (Whitty et al., 2020).

Reaching all groups affected

We recognise that this survey did not reach all groups of people who had been informed they were vulnerable and at high risk of severe COVID-19 complications. Every effort should be made for any future research and – most importantly – for any mitigations to be offered to marginalised groups who may be hard to reach. This includes those who may be reluctant to engage with mainstream care as a result of negative experiences that have led to mistrust in healthcare provision, or through being from groups who may be overlooked in terms of equitable access and inclusion in healthcare provision and research.

People with chronic health conditions, intellectual disabilities (Hatton & Hastings, 2020; Sodha, 2022) and from ethnic groups who have experienced marginalisation and poverty held high levels of mistrust in the UK health system during the pandemic (Gillibrand et al., 2024). This has been researched in the context of vaccination engagement but there are few studies of the impact of continued shielding in those who remain CEV. Research has found that, for example, people with sickle cell disease in the UK reported similar experiences to the Forgotten Lives UK patients and their families in terms of feeling let down by healthcare professionals, and left to fend for themselves while the majority of the population returned to their normal lives (Berghs et al., 2022; Versus Arthritis, 2023).

The NHS puts an emphasis on promoting inclusion health, and on reaching people who are socially excluded. Typically, they may have multiple and overlapping risk factors, such as poor health, poverty and complex trauma. It is important to recognise the obstacles presented when groups have been marginalised socially and medically and how this may impact on being part of wider patient groups and studies (Health Research Authority & Medical Research Council, 2022). Therefore, our findings need to be considered within the NHS Inclusion Health Framework (NHS England, n.d.-a, 2024b) and applied to an even wider group of patients and their families and those with additional cultural and disease-specific factors, some of which may produce even more barriers in obtaining help, in particular psychological support.

Helping healthcare staff to support immunocompromised patients

We acknowledge the huge additional demands placed on healthcare professionals by the pandemic and the ongoing legacy of COVID-19. However, we are concerned by the multiple accounts shared in this survey of patients feeling dismissed and feeling unsupported and misunderstood by their medical teams, despite following patient guidance that was provided by the government and the NHS to those who were and who remain CEV. In this regard, we fully support and agree with Versus Arthritis' recommendation on page 37 of the *Shielding Voices* report:

Finally, there is the longer-term effect on shielders' relationship with healthcare professionals. People who are shielding feel that clinicians were not wholly equipped to support them during this uncertain period. Therefore, clinicians may need support to understand people's altered perceptions of themselves, of their place in society and how they may need help from healthcare professionals in understanding their personal risk from COVID-19. This latter point is a challenge for clinicians – at the beginning of the pandemic evidence regarding both population-level and personalised risk was not already available. Currently, we have much more understanding about vaccine efficacy and who remains at highest risk from COVID-19, but providing this information to individual patients in a way that is meaningful to them, poses a challenge [page 37].(Versus Arthritis, 2023)

Clinical health psychologists working with patient and family groups and the specialist medical societies are very well placed to lead on this; it is part of their core work to bridge the conversations between healthcare professionals, medical groups and patients – and to provide therapeutic interventions to support and assist with people's very challenging situations. ACP-UK would be happy to be involved in this work and is well situated to work across different medical specialties, with the Royal Colleges and specialist medical societies.

Summary of Recommendations

- Shared decision making between patients and their healthcare professionals
- Improved training and support for healthcare staff to care for immunocompromised patients in a consistent and appropriate way
- Introduction of a flagging system to identify immunocompromised patients to healthcare staff
- Add immunocompromised patients to the NHS England Risk Registers
- A national government response to meet the needs of immunocompromised patients and their families
- Strenuous efforts to reach all patients including those in marginalised groups to provide secondary treatments
- Increased availability of suitable psychological and mental health support and treatment for patients and their family members
- Access to work and employment support

Continuing the work

There is much to put in place to assist immunocompromised patients and their family members, including the provision of robust psychological support pathways on an equitable basis across specialties and across the country. As well as sharing feelings of anger, heartbreak and desperation, some of the survey respondents wanted to share their thanks for everyone working to improve their situation. We share one of their messages here to acknowledge all the work being done and that will continue to take place in the future to try to give the patients and their families their normality once again:

> ***"I just want to thank everyone behind organising this survey, the NICE review, and all the research, time and love that goes into developing treatments like Evusheld and pushing for our forgotten lives. I am so very grateful."***

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