International COVID-19 Blood Cancer Coalition (ICBCC)

PATIENT IMPACT STATEMENT AND RECOMMENDATIONS
Protecting immunocompromised blood cancer patients from COVID-19

Date of release: 31st May 2023

In late 2021, a multi-stakeholder coalition consisting of representatives from the global patient advocacy and clinical community formed the International COVID-19 Blood Cancer Coalition (ICBCC) to address the specific impact of COVID-19 on immunocompromised blood cancer patients (both acute and chronic), like those living with Chronic Lymphocytic Leukemia (CLL) and other Non-Hodgkin lymphomas (NHLs). In February 2022, the ICBCC released its first Joint Patient Impact Statement. The purpose of this statement was to aid when advocating for the provision of anti-COVID-19 treatment and care for immunocompromised (IC) blood cancer patients, recommending practical solutions and actions to mitigate risks. While COVID-19 seems to have become a less severe problem for most populations, some groups like blood cancer patients remain at elevated risk with some profound effects on their lives, and the gradient nature of such risk is not properly acknowledged.

Following on from the previous version of the ICBCC Joint Patient Impact Statement, which focused on recommendations for governments and health authorities, this revised statement discusses helping patients help themselves so they can re-engage with the world. As a significant stressor[xi], the COVID-19 pandemic has resulted in the **deterioration of mental health** in some patient groups[x,xv], specifically multiple stressing factors of being immunocompromised, being less protected than others, and continuation of shielding from the environment and the impact of social isolation, despite the relaxation or even abolishment of public rules. One community-led research found that stress levels were often higher in the patient's partner than the patient themselves[xvii].

The Problem

The estimated share of those who are immunocompromised or immunosuppressed (IC/IS) is between 2% and 3% percent of the total global population. Their condition results in vulnerability to contracting and suffering poor outcomes with COVID-19. Sadly, during the last three years their circumstances have been neglected to a larger or smaller extent with marked differences across geographical locations, leaving some to call them the "Prisoners of the Pandemic". Even with significant progresses and health gains through vaccination and sheltering, IC/IS patients have seen far fewer benefits and are still suffering from the physical and psychological impact of COVID-19. Their challenges include the consequences of long-term isolation, the risk of long-COVID for cancer patients in general[xv], and difficulties in treatment and care for both COVID-19 and other medical conditions once they contract COVID-19.

Their antibody responses to COVID-19 vaccines and even boosters have been repeatedly proven to be less predictable and robust when compared to the general population[i,ii,iii]. There is evidence that boosters do yield benefits for people living with hematologic malignancies[xiii], but response to boosters may still be suboptimal in blood cancer patient populations. The various virus strains now circulating may also present different levels of risk of severe side effects resulting from breakthrough infection. These uncertainties lead to more insecurity[xvi] overall for patients. Therefore, a layered approach to protection and mitigating risk including boosters and other measures is recommended.

What we do know is that immunocompromised / immunosuppressed (IC/IS) patients[1] in general, and blood cancer patients in particular, have:

1. Greater risk[xxi,xxii] from COVID-19 including higher rates of hospitalization, ICU admissions and death[iv].
2. Higher rates of breakthrough infections after being fully vaccinated[v].
3. No simple lab test to reliably predict protection post vaccination, and difficulties in accessing testing options.
4. Shown in some cases to carry and shed severe acute respiratory syndrome coronavirus 2 (or SARS-CoV-2) for months leading to the risk of introducing potentially dangerous new mutations into the broader population[vi].

While ~97% of the adult population has the option of a safe and extremely effective way to prevent severe COVID-19 and can re-engage in the world by getting vaccinated, the vulnerable 2-3%, namely the IC/IS patients, continue to be cautioned by local and global health authorities that vaccines may only give partial protection[vii].

Also, the definition of who is considered immunocompromised is unclear and absent of precise diagnostic and clinical indicators, while this lack of clarity may also create confusion in patient communities about whether they are at higher risk or not. One example is those with CLL who have long been recognized as being significantly immunocompromised at all stages of disease, regardless of their treatment status[viii]. Quoting from a recent study of COVID-19 vaccine response in blood cancer patients by The Leukemia & Lymphoma Society: "More than one-third (36%) of patients with CLL, the most common leukemia in U.S. adults, were seronegative after two mRNA vaccines. Nearly three in ten of them had no cancer therapy in the past two years, showing that the disease itself may impair the B cell function needed to make antibodies to vaccines." [ix] The lack of a humoral response can persist after a third booster vaccination. Moreover, we know that we can't rely on any single blood test to determine vulnerability to COVID-19.

Recent research[xxiii] discusses the detrimental effects of loneliness and social isolation and their impact on mental and physical health. The long-term sheltering and isolation of IC/IS patients is likely to compound the challenges they already face, and so it is essential that they can re-engage with the world in a safe way.

Principles

The new mantra of "***Get vaccinated & be mindful of and understand your risks"*** seems to work to some extent for IC/IS populations. Patients should be encouraged to discuss their individual circumstances with their healthcare providers in order to engage back in the world. Some settings may be safer than others, and there needs to be a balanced approach to deciding how and when to relax individual safety measures. This requires efforts from both the patients and society, and we cannot expect IC/IS patients to remain locked down indefinitely, thus turning their IC/IS status into a hidden disability.

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[1] For the purposes of this statement, we use this definition of immunocompromised: Having a weakened immune system can make you more likely to get severely ill from COVID-19. Many conditions and treatments can cause a person to be immunocompromised or have a weakened immune system. Primary immunodeficiency is caused by genetic defects that can be inherited. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html

The special vulnerability of those with blood cancers and others needs to be addressed in a proactive way. Certain principles can inform best practices for the IC/IS community:

1. We recognize that there is public fatigue with health measures and even the conversation around COVID-19.
2. Public awareness of issues IC/IS patients face is important.
3. IC/IS blood cancer patients must be included in the priority treatment groups with those considered at high risk and most vulnerable to COVID-19 infection. **Everyone, regardless of their immune status, should be vaccinated.** The more people are vaccinated, including booster vaccine doses, the more the IC/IS are protected.
4. **Risk awareness and assessment:** both patients with a diagnosis that renders them immunocompromised or immunosuppressed, as well as healthcare professionals should know, understand and assess the risk appropriately so that it can inform response and management.
5. Strategies and actions for IC/IS need to rely on antivirals and COVID-19 monoclonal antibodies (CmAbs). Relevant research going on in the fields of prophylactics and therapeutic antibodies needs to be encouraged.
6. IC/IS patients need to **re-engage with the world** to ensure their overall mental and physical wellbeing; however, they need support to help them do so.
7. **Safety measures and masking should continue to be maintained in any clinical setting when treating IC/IS patients** even when public rules are being relaxed.

Recommendations

ICBCC is developing an information campaign to help patients play their part by managing their risk according to their individual circumstances when reengaging with the world. The following recommendations are aimed at providing support to patients and are aimed at all stakeholders that can meaningfully contribute to the mitigation of risks together with patients by making information available: governments, pharmaceutical companies, researchers, and policy makers.

1. **Access to fast response COVID-19 testing for high-risk patients**[xvi]. Many of the lifesaving therapies must be instituted quickly after diagnosis to be effective. Waiting a week for the results of a PCR test could be a fatal delay. Possible solutions include:
    a. Special access to home tests for the IC/IS community.
    b. Testing slots set aside or special testing sites for the IC/IS.
    c. Systems should be in place at national level to process the IC/IS that test positive to COVID-19 to ensure a quick access to treatment like nirmatrelvir/ritonavir and other options[xviii].
2. **Managing risks:** The real-world research of risks and the effectiveness of different responses to them needs to continue[xx].
3. **Masking** needs to be continued in healthcare facilities that treat IC/IS patients.
4. **Access to Pre-Exposure Prophylaxis or PrEP and Post Exposure Prophylaxis or PEP, and antivirals for high-risk patients**. When vaccination doesn't provide protection, there must be adequate access to appropriate therapies to prevent and treat infections. As some existing treatment options like tixagevimab/cilgavimab have proven to be less effective than expected for recent virus variants, **research into new options** needs to intensify.

5. **Using scientific rigor to best define who is at high risk for COVID-19.** It cannot be based on a single blood value and instead should be informed by the increasing volume of scientific literature on COVID-19 outcomes in several different IC/IS communities. This is especially true for all those with lymphoid malignancies including many lymphomas such as CLL/SLL (chronic lymphocytic leukemia/small lymphocytic lymphoma) and other NHLs, regardless of whether they are before, during or after treatment.
6. **Ensuring equitable access to best practices and treatments as well as affordable PPE and COVID-19 tests** regardless of geographic, socio-economic, racial or ethnic considerations.
7. All those who might benefit should be offered additional or **"booster" vaccine doses**[xii]. Booster vaccine doses should be offered **especially to the elderly and immunocompromised** based on studies demonstrating their protective benefits.
8. **Involvement of the medical institutions in low-and middle-income countries** into the clinical studies / trials of new anti-COVID-19 medications.
9. **Provision of psychological support services** specifically to the immunocompromised who need to continue shielding and social distancing despite the relaxation of public rules[xiv]. Offering the right protective measures complete with a comprehensive strategy to assess risks, to protect the patients from the multiple stressing factors of being immunocompromised, being in lockdown or otherwise shielding from the environment will lead to better physical and mental health outcomes.
10. **Vaccines must be made available globally**, not only in high income countries. Reliable information about vaccines and treatments should be made available and more visible.
11. **Educating IC/IS patients** that continued masking and social distancing in high-risk circumstances, and also on proper individual risk assessment is essential even if the public rules on masking and social distancing are abolished.

Until there is enough antiviral and antibody therapy for all who might benefit, difficult choices will need to be made to ensure equitable access.

Protecting the immunocompromised where the virus has proven to linger and mutate, protects everyone[xii].

COVID-19 management has changed fundamentally. While this represents the consensus as to best practices at the time of its publication, new options will require ongoing updates. And so, it is also essential to ramp up research into identifying the factors of neglected care for the broader patient community of IC/IS patients.

Thank you for considering the needs of this large population that has been largely forgotten during and after the pandemic.

On behalf of the International COVID-19 Blood Cancer Coalition (ICBCC)

31st May 2023

Endorsed by:

Global /European Patient Organisations:

CLL Advocates Network
(Global)

The MDS Alliance
(Global)

Lymphoma Coalition
(Global)

CML Advocates Network
(Global)

Acute Leukemia Advocates Network,
ALAN
(Global)

Myeloma Patients Europe, MPE
(Europe)

European Cancer Organisation
(Europe)

National Patient Organisations

Leukaemia Foundation
(Australia)

Lymphoma Australia
(Australia)

The Leukemia & Lymphoma Society
(USA)

Lymphoma and Leukemia
Foundation of Barbados
(Barbados)

Lymphoma Association Flanders
(Belgium)

CLL Canada
(Canada)

The Leukemia & Lymphoma
Society of Canada
(Canada)

AGALEMO
(Costa Rica)

Hrvatska Udruga Leukemija i Limfomi,
HULL
(Croatia)

Fundación Esperanza Viva
(Colombia)

Diagnóza Leukemie
(Czech Republic)

Patient Advocacy Group for
Lymphoma, Leukemia and MDS, LyLe
(Denmark)

Ensemble Leucémie Lymphomes Espoir - ELLyE
(France)

Deutsche Leukämie- und Lymphom-Hilfe, DLH
(Germany)

Leukämie Online
(Germany)

LeukaNET
(Germany)

Hellenic Group of Patients with Chronic Lymphocytic Leukemia
(Greece)

V Care
(India)

CLL Ireland
(Ireland)

Irish Cancer Society
(Ireland)

Flute of Light - Home of blood cancer patients in Israel
(Israel)

HEMA-ONCO
(Macedonia)

Mexican Association of the Fight Against Cancer (AMLCC)
(Mexico)

AMAL
(Morocco)

Blood Cancer Society Nepal
(Nepal)

Hematon
(The Netherlands)

Leukaemia & Blood Cancer New Zealand
(New Zealand)

CLL Advocates New Zealand, CLLANZ
(New Zealand)

Inter-regional public organization for patients with hematological diseases «Most Miloserdiya» («Mercy Bridge»)
(Russia)

Maja Kocic, President
Lymphoma Patient Association LYPA / LIPA
(Serbia)

AELCLES (Spanish Network for Leukemia and Blood Disorder)
(Spain)

Blodcancerförbundet / The Swedish Blood Cancer Association
(Sweden)

Slovenian Lymphoma and Leukemia Patient Association, L&L
(Slovenia)

SFK- Stiftung zur Förderung der Knochenmarktransplantion
(Switzerland)

Lymphome.ch Patientennetz Schweiz
(Switzerland)

Blood Cancer Foundation of Tanzania (BCFT)
(Tanzania)

Follicular Lymphoma Foundation
(UK)

Leukaemia Care
(UK)

Lymphoma Action
(UK)

Leukaemia & Lymphoma NI
(UK)

CLL Support
(UK)

Blood Cancer UK
(UK)

MDS UK Patient Support
(UK)

CLL Society
(USA)

Patient Power
(USA)

Blood Cancer Uncensored
(UK / USA / Canada)

Charity Fund of patients
“Drop of Blood”
(Ukraine)

Clinical community / Medical Societies:

European Hematology Association,
EHA
(Europe)

European Research Initiative on CLL,
ERIC
(Europe)

International Workshop on Chronic
Lymphocytic Leukemia (iwCLL)
(Global)

AHA - Armenian Hematology
Association
(Armenia)

Peter MacCallum Cancer Centre
(Australia)

Dr Versha Banerji, Physician
(Canada)

Dr Alina Gerrie, Hematologist
British Columbia
(Canada)

French Innovative Leukemia
Organization
(France)

Institute of Applied Biosciences
CERTH - Center for Research and
Technology Hellas
(Greece)

GIMEMA
(Italy)

Dr Tamar Tadmor, Physician
The Israeli CLL Study Group (Israel)

Dr Vasile Musteata, Physician
State University of Medicine and
Pharmacy "N. Testemitanu" (Moldavia)

UK CLL Forum
(UK)

Prof Paul Moss, Physician
Chief Investigator of the CLL-Vaccine
Response Study, Birmingham (UK)

British Society for Hematology
(UK)

UK MDS Forum
(UK)

Anne Crook, Counsellor /
Psychotherapist, Psycho-oncology
(UK)

Nicole Lamanna, MD
Director CLL Program
Hematologic Malignancies Section
Herbert Irving Comprehensive Cancer Center
New York-Presbyterian/Columbia University Medical Center
(USA)

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