International COVID-19 Blood Cancer Coalition (ICBCC)

PATIENT IMPACT STATEMENT AND RECOMMENDATIONS
Protecting immunocompromised blood cancer patients during the COVID-19 pandemic

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A multi-stakeholder coalition consisting of representatives from the global patient advocacy and clinical community has formed the International COVID-19 Blood Cancer Coalition (ICBCC) to address the specific impact of the pandemic on immunocompromised blood cancer patients (both acute and chronic), and to recommend solutions and actions to mitigate those risks.

The Problem

The estimated share of those who are immunocompromised (IC) is between two and three percent of the total global population. All are more vulnerable to contracting and suffering poor outcomes with COVID-19. Sadly, during the last two 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".

Their antibody responses to COVID-19 vaccines and even boosters have been repeatedly proven less predictable and robust when compared to the general population[i, ii, iii, xxiii, xxiv, xxv, xxviii]. However, there is also evidence that boosters do yield benefits for people living with hematologic malignancies[xiii, xxvi].

What is known is that immunocompromised (IC) patients[1] in general, and blood cancer patients in particular, have:

1. Much greater risk from COVID-19 including higher rates of hospitalization, ICU admissions and death[iv, xviii, xix, xx, xxi, xxii].
2. Higher rates of breakthrough infections after being fully vaccinated[v].
3. Higher rates of their infection spreading to household contacts.
4. No simple lab test to reliably predict protection post vaccination.
5. 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 patients, continue to be cautioned by local and global health authorities not to rely on vaccines for protection[vii].

[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 definition of who is considered immunocompromised is unclear and absent of precise diagnostic and clinical indicators. One example is those with Chronic Lymphocytic Leukemia (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: "More than one-third (36%) of patients with CLL, the most common leukemia in U.S. adults, were seronegative after vaccination. 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] Moreover, we know that we cannot rely on any single blood test to determine vulnerability to COVID-19.

As a significant stressor, the COVID-19 pandemic has also resulted in the **deterioration of mental health** in some patient groups[x, xv, xxvii], specifically multiple stressing factors of being immunocompromised, being less protected than others, and continuation of shielding from the environment, despite the relaxation of public rules.

Principles

The mantra of "***Get vaccinated, but act as if you are not"*** is an appropriate interim solution. However, IC patients should not be expected to remain locked down indefinitely as the rest of the world returns to near normal.

The special vulnerability of those with blood cancers and others needs to be addressed in a proactive way. While needing to be prepared for surprises when dealing with COVID-19, certain principles can inform best practices for the IC community:

1. There is public fatigue with health measures.
2. Public awareness of issues for IC is important.
3. IC 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 active immunity from a vaccine is preferred for those who can rely on it. The more people are vaccinated, including booster vaccine doses, the more the IC are protected.
4. Strategies and actions for IC need to rely on post-exposure antivirals and pre-exposure COVID-19 monoclonal antibodies (CmAbs).
5. **Educating the IC patients that continued masking and social distancing** in high-risk circumstances are essential even if the public rules on masking and social distancing are relaxed. This is especially true in settings where the IC will likely be present such as during public transit and in public buildings.
6. **Safety measures and masking should continue to be maintained in any clinical setting when treating IC patients** even when public rules are being relaxed.

Recommendations

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 community.
    b. Testing slots set aside or special testing sites for the IC.
    c. Systems should be in place at national level to process the IC that test positive to COVID-19 to ensure a quick access to treatment.

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2. **Access to Pre-Exposure Prophylaxis or PrEP and Post Exposure Prophylaxis or PEP, and antivirals for high-risk patients**. When vaccination does not provide protection, there must be adequate access to appropriate therapies to prevent and treat infections. A critical claim, it can be achieved by accelerating the production and equitable distribution of antivirals and CmAbs. There are good options but scarce supplies.
3. **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 communities. This is especially true for all those with lymphoid malignancies including many lymphomas such as CLL/SLL (chronic lymphocytic leukemia/small lymphocytic lymphoma), regardless of whether they are before, during or after treatment.
4. **More research** is needed about blood cancer and IC patients and existing and future antivirals.
5. **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.
6. All those who might benefit should be offered additional **vaccine doses**[xii]. Booster vaccine doses should be offered **especially to the elderly and immunocompromised** based on studies demonstrating their protective benefits
7. **Involvement of the medical institutions in low and middle income countries** in the clinical studies / trials of new anti-COVID-19 medications.
8. **Provision of psychological and psycho-oncological 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 protect the patients from the multiple stressing factors of being immunocompromised, less protected than others, being in lockdown or otherwise shielding from the environment will lead to better physical and mental health outcomes.
9. **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.

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 most vulnerable is not only the right thing to do, but also the smart thing to do. Protecting the immunocompromised where the virus has proven to linger and mutate, protects everyone[xii].

COVID-19 management is changing rapidly. 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 patients.

Thank you for considering the needs of this large population who have been largely forgotten during the pandemic.

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

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Further Reading:

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