



VIA EMAIL

September 20, 2021

Rochelle P. Walensky, M.D., M.P.H.
Director, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS H24-8
Atlanta, GA, 30329-4027

Re: SARS-CoV-2 Revaccination for persons who have received a hematopoietic cell transplant or cellular therapy

On behalf of National Marrow Donor Program (NMDP)/Be The Match (BTM), American Society for Transplantation and Cellular Therapies (ASTCT), and Center for International Blood and Marrow Transplant Research (CIBMTR), we are writing to bring attention to the urgent issue of revaccination for persons who have received either hematopoietic cell transplantation (HCT) using bone marrow, peripheral blood, or umbilical cord stem cells or cellular therapy (CT), most notably chimeric antigen receptor (CAR) T cells, despite having received SARS-CoV-2 vaccine prior to HCT/CT.

Depending upon its level of intensity, the conditioning regimen associated with HCT/CT suppresses or even eliminates completely a patient's immune system. In addition, immune recovery after transplant is often delayed or aberrant. Lastly, immunosuppression associated with allogeneic transplantation further suppresses immune response. Collectively, these processes predispose HCT/CT patients to significant infection-related morbidity and mortality. Consequently, HCT/CT patients are at significant risk for severe COVID-19, which associates with increased mortality risk.^{1,2}

In the general population, the safety and efficacy profiles of the SARS-CoV-2 vaccines are well established.³⁻⁵ In the HCT/CT population, the SARS-CoV-2 vaccines are safe, but their inducible immunogenicity is attenuated by underlying immune aberrancy and/or suppression.^{6,7} As a result, HCT/CT patients require booster vaccination as recognized by both the Centers for Disease Control and Prevention (CDC)⁸ and Food and Drug Administration (FDA).⁹

Given the significant risk to develop severe COVID-19 in immunocompromised patients, the established safety profile of the SARS-CoV-2 vaccines in HCT/CT patients,¹⁰ and the attenuated immune response to SARS-CoV-2 vaccination requiring booster vaccine in HCT/CT patients, ***we strongly recommend that patients who received SARS-CoV-2 vaccine prior to their transplant or cellular therapy need revaccination following HCT/CT.*** In fact, revaccination after HCT/CT is standard of care and follows best practices to protect patients from preventable diseases, like pneumococcal infections.¹¹

The CDC has been an instrumental partner in our pandemic response to date. The CDC and Advisory Committee on Immunization Practices (ACIP) were essential in updating the CDC's guidance of "People with Certain Medical Conditions" to reflect referenced studies indicating that the HCT/CT population *are* at increased risk for complications for COVID-19 (when the guidance originally said these patients *might* be at risk).¹²

Our organizations greatly appreciate the CDC for upgrading the risk profile of our patients.



Stakeholder Organizations:

Our organizations represent the HCT/CT communities throughout the United States. We work daily to assist patients and their families, so they can access these life-saving, but high-risk treatments.

ASTCT is an international professional membership association of more than 2,600 physicians, investigators and other health care professionals from more than 45 countries. Our mission is dedicated to improving the application and success of blood and marrow transplantation and related cellular therapies.

CIBMTR is a research collaboration between the National Marrow Donor Program® (NMDP)/Be The Match® and the Medical College of Wisconsin (MCW). The CIBMTR collaborates with the global scientific community to advance HCT and other cellular therapy worldwide to increase survival and enrich quality of life for patients.

NMDP/BTM is entrusted by Congress to operate the C.W. Bill Young Cell Transplantation Program that matches unrelated volunteer stem cell donors with patients in the United States and abroad who have been diagnosed with hematologic malignancies as well as more than 70 otherwise fatal blood disorders and diseases. Our mission is to save lives through cellular therapy.

Collectively, our organizations partner to collaborate in reducing barriers for blood cancer and blood disease patients and optimizing their survival.

Clinical Impact:

HCT/CT patients who need revaccination with SARS-CoV-2 vaccines are being denied by state health departments, or authorized vaccination providers due to their having previously received vaccination prior to transplant or cellular therapy. Currently, healthcare providers are not authorized under the Emergency Use Authorization (EAU) to revaccinate HCT/CT patients due to current CDC guidance.

Request:

Throughout the pandemic, the CDC has been a critical partner in supporting our patients. Therefore, ***we ask for the CDC's help in protecting previously vaccinated patients who now require HCT/CT against severe COVID-19 by explicitly supporting SARS-CoV-2 revaccination following hematopoietic cell transplantation or cellular therapy.***

On behalf of our patients, their caregivers, and their donors, we thank you for the consideration of this request.

Please contact Dr. Jeffery Auletta, Senior Vice President, NMDP/BTM & Chief Scientific Director, CIBMTR NMDP at call 1-800-627-7692 for any additional information you may require.



Sincerely,

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