

October 26, 2020

Dr. Robert R. Redfield
Director
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS H24-8
Atlanta, GA, 30329-4027.

c/o Attention: October ACIP Meeting

Re: Docket No. CDC-2020-0100

Dear Director Redfield, Agency Staff and Advisory Committee on Immunization Practices:

National Marrow Donor Program (NMDP)/ Be The Match is pleased to submit comments to the Centers for Disease Control (CDC) regarding provisions of the Advisory Committee on Immunization Practices (ACIP) and the COVID-19 vaccine distribution plan and recommendations.

Background

NMDP is entrusted by Congress to operate the C.W. Bill Young Cell Transplantation Program that matches unrelated volunteer bone marrow donors with patients in the United States and abroad who have been diagnosed with leukemia, lymphoma, as well as more than 70 otherwise fatal blood disorders and diseases. Under contract with the Department of Health and Human Services/Health Resources & Services Administration (HRSA), the Program is charged with providing equal access for all patients in need of a life-saving cellular therapy. NMDP works to facilitate the timely delivery of bone marrow and other cellular therapies for more than 6,600 patients every year. In addition to matching donors and patients, another of the Program's primary missions is coordinating the domestic and international delivery of donated bone marrow to patients in the United States and abroad.

CDC has played a critical role in ensuring the uninterrupted movement of bone marrow and other cellular therapies during the COVID pandemic. We would especially like to thank the CDC for its quick help in issuing a waiver in the national interest to allow European bone marrow couriers to transport cellular therapies to American patients. Because of this action in the first days of the public health emergency, along with the support of other Federal agencies, including our partners at the Department of Health and Human Services and HRSA, the Assistant Secretary for Preparedness and Response (ASPR), the Department of Homeland Security, Customs and Border Patrol, and the Department of State, our Program has not missed delivery of a single donation of lifesaving cells over the past eight months. In fact, in the months following the issuance of the travel ban waiver by the CDC, NMDP has been able to secure delivery of more than 530 urgent, life-saving transplants to occur uninterrupted from overseas donors.

Comments

The Essential Critical Infrastructure Workers Guidance Version 4.0 by Cyber Security and Infrastructure Security Agency (CISA), under the Department of Homeland Security, provided early and necessary guidance on how critical infrastructure owners could prioritize essential workers to “work safely while supporting ongoing infrastructure operations across the nation.” The most recent version identifies essential workers that require specialized risk management strategies to ensure that they can work safely. In addition, the CISA guidance can be used to “begin planning and preparing for the allocation of scarce resources used to protect essential workers against COVID-19.” This guidance was critical to NMDP/Be The Match, in part thanks to the directive issued by CDC, because it includes “Donors of blood, bone marrow, blood stem cell, or plasma, and the workers of the organizations that operate and manage related activities” as essential healthcare workers.¹ This life-saving designation has been key to eliminating delays in delivering lifesaving cellular therapies to waiting patients.

After reviewing, National Academies of Sciences, Engineering, and Medicine 2020 Framework for Equitable Allocation of COVID-19 Vaccine, as well as ACIP COVID-19 Vaccine Work Group Phase 1 allocation of COVID-19 Vaccine, NMDP felt it necessary to provide additional clarification regarding the essential roles of donors, couriers and caregivers within our healthcare system as it relates to bone marrow transplant and the immunocompromised position of our patients which places them in the category of “high risk medical conditions.”²

Each year, more than 18,000 patients may need a bone marrow or peripheral blood stem cell (PBSC) transplant. Of those, only 30 percent will have a matched donor in their family. For the remaining 70 percent of patients, an unrelated donor is their only hope for a cure. In the United States, we work with more than 5,000 potential volunteer bone marrow donors every year to help these patients in need of an unrelated donor.

In order to deliver these lifesaving donated cells, trained couriers travel to the donation site to hand-carry bone marrow and PBSCs in the passenger compartment of scheduled commercial flights to the transplant center where the patient is being treated. If the transportation of donor cells (which have an efficacious shelf-life of less than 72 hours) is interrupted, the consequences are fatal. Patients awaiting these deliveries are amid scheduled courses of chemotherapy and radiation to ablate their immune systems in preparation for the transplant of donated cells to create a healthy, new immune system. Failure to timely deliver the donated cells to these patients would be catastrophic and, in the vast majority of instances, life ending. There is no aspect of NMDP’s work that is elective or non-essential for our patients.

¹ See <https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce> (accessed September 15, 2020).

² National Academies of Sciences, Engineering, and Medicine 2020. Framework for Equitable Allocation of COVID-19 Vaccine. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25917>
Dooling, Kathleen, MD MPH. “ACIP COVID-19 Vaccine Work Group. “Phase 1 allocation COVID-19 Vaccine Work Group Considerations. September 22, 2020

More than 3,000 of these cellular therapy products cross international borders annually. We currently have nearly 600 couriers in the United States ready at a moment's notice to assist in delivering these cells. Difficulties have arisen with foreign countries because of various forms of travel restrictions and restrictions into countries that include COVID testing requirements and quarantine.

Couriers are a key link in the network that provides bone marrow donations to patients that should be included under ACIP's Phase 1a grouping to provide vaccines to Health Care Providers. ACIP defines healthcare personnel as "all paid and unpaid persons in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials. This includes persons not directly involved in patient care but potentially exposed to infectious agents while working in a healthcare setting." As mentioned earlier, donors have received CISA classification as Critical Infrastructure.

We believe it is of paramount importance to provide vaccines to couriers who are completing essential health care work to protect the health of these volunteer couriers, to continue to facilitate timely travel authorizations for individual courier travel, and to coordinate private and/or humanitarian flights into and out of countries that have closed their borders to international travel. To guarantee and expedite couriers' ability to deliver these cells, NMDP believes that couriers meet ACIP's definition of "all paid and unpaid persons serving in the healthcare settings who have potential for direct or indirect exposure to patients or infectious materials." Therefore, we request that this crucial link in the chain that brings life-saving cells to a patient be included in the first phase of the vaccine distribution.

A second key link in the network includes the donors themselves. For the same previously stated reasons as couriers, we believe that volunteer donors also should be considered under ACIP's Phase 1a grouping to provide vaccines to Health Care Providers. NMDP/Be The Match relies on our volunteer donors, who undergo medical procedures in order to provide a lifesaving cells for a patient in need. The patients in need often begin chemotherapy and radiation several days prior to the volunteer donor actually donating. This preparative treatment is given to provide immunosuppression to prevent rejection of transplanted cells and to eradicate underlying disease for which the transplant is being performed. It is critical that donors remain healthy and available leading up to transplant. If a donor were to contract COVID-19 during this time period, a patient may not receive lifesaving cells and would be left in a severely immunosuppressed state susceptible to infections which are often life-threatening. By ensuring our donors are vaccinated for COVID-19 we can ensure this sensitive period of time is as safe as possible, and also ensure our volunteer donors are well taken care of. Due to COVID-19, NMDP has experienced several situations where a patient's life was put at risk because of a donor's exposure or diagnoses with COVID. Given the critical and time sensitive nature of the service our donors provide, we respectfully ask that donors of bone marrow and PBSC be given vaccines in the first phase of the vaccine distribution.

We also would request that consideration be given for including patients requiring bone marrow transplantation therapy under ACIP's Phase 1b grouping to provide vaccines for those with High Risk Medical Conditions. A presentation by the ACIP COVID-19 Vaccine Work Group regarding the Phase 1 allocation of COVID-19 vaccine considerations included among the list of

“Adults with medical conditions at higher risk” individuals who are in an “immunocompromised state from a solid organ transplant.” We recommend that bone marrow transplant patients, who also are immunocompromised, be included in the same category as solid organ recipients.³

Finally, we would request that consideration be given for including full-time caregivers for patients requiring bone marrow transplantation therapy under ACIP’s Phase 1a or 1b grouping to provide vaccines for Health Care Providers or for those with High Risk Medical Conditions. Unique to the bone marrow transplant population is the requirement for patients to have a full-time caregiver staying with the patient 24 hours a day, 7 days a week for the first 100 days after transplant. In many cases they serve as caregivers for 6 months or longer. The Johns Hopkins University Center for Health Security released in August an interim framework for COVID-19 vaccine allocation and distribution in the United States. It recommends that those at greatest risk of severe illness, *and their caregivers*, should be included in the highest priority vaccine distribution group⁴. These caregivers must be ready to drop what they are doing at a moment’s notice and bring the patient to the hospital if they have signs of complications, such as fever, shortness of breath, or dizziness. Other responsibilities include managing medications (often more than 20), assisting with activities of daily living, changing dressings, and coordinating appointments with the health care team. Caregivers are often close family members (spouse, parent, adult children) or friends who have stepped away from work or school to serve in this full-time role. While caregivers of bone marrow transplant patients may be isolated to some degree from COVID-19 due to their intense caregiving duties, they accompany patients to medical appointments, pick up prescriptions, and run other essential errands which carry a risk of community exposure. Obviously, if a caregiver becomes ill, the patient is at risk of also becoming ill. In this case, a caregiver would not be able to continue to care for the patient and another caregiver must be identified on short notice, which in the worst case could further expose the patient to COVID-19. A vaccine is required to afford every protection available to caregivers as a further line of defense against infecting immunocompromised patients.

Conclusion


NMDP thanks CDC for its leadership and rapid action in response to the COVID-19 pandemic, including its support for our lifesaving work over the past eight months. Furthermore, we appreciate the opportunity to submit these comments regarding the Phase 1 allocation of a COVID vaccine. We would ask the Administration and your Advisory Committee on Immunization Practices to continue to partner with NMDP in helping to ensure the on-time delivery of these life-saving therapies to those most in need of treatment. Specifically, we believe that it is in the national interest to clarify that volunteers who donate and courier cellular therapy products, the patients who receive these therapies, and their caregivers should be considered as Essential Health Care Personnel and Adults with High Risk Medical Conditions to make them eligible for the Phase 1 allocation of the COVID-19 vaccine.

³ Dooling, Kathleen, MD MPH. “ACIP COVID-19 Vaccine Work Group. “Phase 1 allocation COVID-19 Vaccine Work Group Considerations. September 22, 2020

⁴ Toner E, Barnill A, Krubiner C, et al. Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States. Baltimore, MD: Johns Hopkins Center for Health Security; 2020.

For more information or to discuss this matter further, please don't contact me at your convenience. Thank you for your consideration.

Sincerely,



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