



Transgender individuals represent an overlooked population amongst stem cell donors

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Approximately 1–1.4 million Americans identify as transgender, a long overlooked and underserved patient population is in the United States [1–3]. Though reporting may underestimate the overall transgender population, the largest age group identifying as transgender is 18–24 years of life, which overlaps considerably with the population of hematopoietic stem cell donors, which tend to be younger individuals [1, 4]. Therefore, considerations must be made for optimal practice in stem cell collection for transgender donors to ensure a safe and healthy collection.

A free language search of the current edition of the Foundation for the Accreditation of Cellular Therapy (FACT) Joint Accreditation Committee (JACIE) International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration only has two standards relating to sex or gender [5]. Standard C6.5 requires retention of donor information related to gender along with other basic demographic information. This verbiage is vague and may lead to oversight on the part of the apheresis or transplant teams, which can be impactful as outcomes vary regarding relapse and graft versus host disease especially in female to male transplants [6, 7]. This may also lead to unanticipated laboratory findings on karyotype and result in questions of specimen mix-up during clinical follow-up [8].

FACT JACIE standards B,C,CM 6.3.4 require a pregnancy test in all female donors within 7 days prior to mobilization, anesthesia, or preparatory regimen, which could lead to unnecessary donor distress or discomfort from

unnecessary diagnostic laboratory testing, or alternatively not investigating pregnancy in individuals born female could be deleterious [9, 10].

Lapses in other accrediting bodies are also evident, the NMDP (National Marrow Donor Program) allows registration of all potential donors and specifies that a donor provide their sex as identified at birth. Though identifying LGBT needs has been recognized as a gap by the NMDP in the Patient-Centered Outcomes Research Agenda, their current standards provide no further guidance for caring for the transgender population [11]. Concurrently, FDA regulations relating to hematopoietic stem cells are regulated under 21 CFR 1271.3(d)(1) and Section 361 of the PHS Act and make no mention of gender or sex of donors.

By not including specific requirements based on gender, the transplant community as a result is somewhat inclusive. However, this is also a missed opportunity to provide compassionate and culturally competent care for these donors who represent an underserved population [3]. Though many of the above-mentioned assertions represent a worst-case scenario in terms of donor management, a lack of consideration for this emerging population may preclude donations and optimal management of these donors. Future regulations should include specific verbiage and guidelines relating to the transgender population.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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