CORRESPONDENCE

Cellular therapy processing laboratory: a workforce hiring nightmare

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TO THE EDITOR:

The COVID-19 pandemic has resulted in innumerable challenges to healthcare in the United States (US), including significant disruptions to hospitals' and clinical laboratories' workforce availability [1]. Notably, some reports have shown that women have been affected and lost or left jobs at higher rates than men, secondary to various factors including decreased childcare options and increased costs for childcare [2]. Further, there is a known, and increasing gap in the current medical laboratory workforce and the number of trained individuals required in the ensuing decades, which has been exacerbated by the COVID-19 pandemic [3]. These medical workforce disturbances, particularly among medical technologists and medical laboratory scientists, have contributed to difficulties in providing critical services to patients with challenging and/or emergent medical conditions.

Multiple reports have delineated the challenges generated by the COVID-19 pandemic and concomitant blood bank workforce shortages on the US blood supply [4–7]. Conversely, within clinical (non-research) cellular therapy laboratories, much is unknown regarding the state of the workforce, although anecdotally, the cellular therapy workforce is also facing a shortage. Cellular and gene therapies are used to induce remission or cure multiple malignant and non-malignant hematologic disorders that may be fatal without treatment. However, notwithstanding the presence of several international independent nonprofit organizations who have developed rigorous standards and regulations for stem cell transplantation programs and cellular therapy laboratories [8–10], the totality of the US clinical cellular therapy laboratory workforce and the associated vacancy rate, retirement rate, and minimum job qualifications continue to be undefined.

These potential cellular therapy laboratory workforce blind spots create recruitment and staffing challenges, as exemplified by limited job description language with the US federal system [11]. The 0644 Clinical Laboratory Science Series lacks specific language outlining the requisite data required for hiring employees within a cellular therapies laboratory, despite listing of technical qualifications for all other clinical laboratory employees, such as those in hematology, bacteriology, mycology, virology, parasitology, immunology, serology, immunohematology, clinical chemistry, and urinalysis. Despite workforce descriptions for both who can be employed, and what functions employees in a cellular therapy laboratory can perform, federal law requires all establishments that manufacture human cells, tissues, and cellular- and tissue-based products, including hematopoietic stem/progenitor cells derived from peripheral, cord blood, and bone marrow, to be registered with the US Food and Drug Administration (FDA) [12]. As such, the physical space of all non-research cellular therapy laboratories in the US is well-defined, yet the quantity and qualifications of the employees within said laboratories are unknown.

These uncertainties in clinical cellular therapy laboratory workforce parameters are already a significant disruption to patient care and the future challenges forecast a daunting tale. The US Health Resources and Services Administration predicts a 19% increase in demand for clinical laboratory technologists by 2030 [13]. Further, the advancement of cellular and gene therapies is ongoing with rapidly expanding FDA-approved medications for chimeric antigen receptor T-cell (CAR-T) therapies (tisagenlecleucel, axicabtagene ciloleucel, brexucabtagene autoleucel, idecabtagene vicleucel, lisocabtagene maraleuce) and gene therapies (voretigene neparvovec-rzyl). Additionally, CAR-T and other manufactured cell therapy products are handled more similarly to pharmaceutical products which requires a different skillset than that required for handling "traditional" hematopoietic progenitor cell (HPC) products.

Moreover, the rate of newly approved cellular therapy medications is anticipated to escalate over the course of the next 3 years, with the FDA predicting upwards of 20 cell and gene therapy products coming to market annually [14]. These investigational cell therapy products require cellular therapy technologists to undergo additional training to learn new processes for handling a variety of products, as each research protocol has a different set of requirements for receiving, storing, thawing, preparing, and infusing the product. Yet, as the demand for HPC and cellular therapy products continues to rise, cellular therapy laboratory processes remain largely manual, and have not benefited from automation unlike many other areas in the clinical laboratory. It is therefore necessary to quantify the number of skilled cellular therapy employees, as any staffing shortage may adversely affect the ability to provide standard of care, and hinder growth and development of novel cellular and gene therapies.

An additional concern is the marked stress and burn-out experienced by individuals across the entirety of the medical field, particularly among medical technologists and those in the clinical laboratory [15, 16]. The laboratory workforce has been involved in the development and implementation of new tests while simultaneously being tasked with significantly increased test volumes and demanding turnaround times [15]. These challenges resulted in over half of American Society of Clinical Pathology (ASCP) medical laboratory workforce survey participants reporting that they were experiencing burnout in 2021, and as a result of feeling burned out, almost one-third of respondents are considering changing careers entirely [15]. The manual nature of the cellular therapy laboratory also raises the concern for risk of repetitive stress injuries, with the risk increasing as the workforce ages.

To meet the demand for cellular therapy laboratory employees, colleges, industry, and regulatory bodies must synergistically

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coordinate and develop new workforce pathways to enhance recruitment, particularly given that many graduates in the biologic sciences may be unaware of the medical technology/medical laboratory science pathway. In the current state, cellular therapy laboratories often recruit medical technologists leaving generalist positions or new graduates without exposure to cellular therapy in their training or clinical rotations. As a result of the lack of exposure or prior experience, training of cellular therapy technologists is more intensive and more protracted compared to other clinical laboratory specialties. The intensity of training is further increased as more complex processes are offered by the cellular therapy laboratory, such as red blood cell reduction of HPC, marrow (HPC(M)), cord blood infusions, and commercial CAR-T cells.

At present, ASCP, which provides the largest global certification program for medical technologists, lacks a specific certification program for cellular therapy [17]. While a joint AABB-George Washington University Cellular Therapy Certificate Program is currently available, it is listed at a price of $1675, which may fall outside the financial reach for entry level laboratory employees, whereas ASCP medical technologist examination fees are listed at $240 [18]. One solution may be to implement financial incentives, particularly focusing on student loan forgiveness and debt relief for individuals pursuing a career in the clinical laboratory [19]. Another method to persuade individuals to enter this field might involve recruitment events ("job fairs") by laboratories and hospitals seeking these professionals, as this approach may provide exposure to job openings that otherwise would go unnoticed. Finally, mentorship programs using virtual platforms could also assist with recruitment to the field, and allow potential candidates to connect with medical technologists who can elucidate what the "day-to-day" life of a cellular therapy technologist is like.

Cellular therapy laboratories currently face challenges in justifying the full-time equivalent needed for the laboratory based on billable charges, which do not accurately reflect the hands-on and time-consuming work required. Failure to invest in the clinical laboratory labor pool will hamper the cellular therapy marketplace, resulting in backlogs of patient care demands and stunted growth for novel cellular therapy products that are urgently needed for patients with hematologic disorders. As such, further research is required to fully quantify staffing levels of clinical cellular therapy laboratories and any potential challenges facing such laboratories in the wake of an ever expanding and rapidly evolving field.

Garrett S. Booth[1]✉, Bipin N. Savani[2], Brian D. Adkins[3], Jennifer S. Woo[4], Rickey Bertram[4], Joel Trushinski[1], Deva Sharma[1,5] and Jeremy W. Jacobs[6]

[1]Department of Pathology, Microbiology and Immunology, Vanderbilt University Medical Center, Nashville, TN, USA. [2]Department of Medicine, Hematology, Stem Cell Transplantation and Cellular Therapy Section, Division of Hematology/Oncology, Vanderbilt University Medical Center and Veterans Affairs Medical Center, Nashville, TN, USA. [3]Department of Pathology, Division of Transfusion Medicine and Hemostasis, University of Texas Southwestern, Dallas, TX, USA. [4]Department of Pathology, City of Hope National Medical Center, Irvine, CA, USA. [5]Division of Hematology/Oncology, Department of Medicine, Vanderbilt-Meharry Center for Excellence in Sickle Cell Disease, Vanderbilt University Medical Center, Nashville, TN, USA. [6]Department of Laboratory Medicine, Yale School of Medicine, New Haven, CT, USA.
✉*email: garrett.s.booth@vumc.org*

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AUTHOR CONTRIBUTIONS

GSB and JWJ performed the research, drafted the manuscript, and revised the manuscript. BNS, BDA, JSW, RB, JT, and DS revised the manuscript. All authors approved the final version.

COMPETING INTERESTS
The authors declare no competing interests.

ADDITIONAL INFORMATION
Correspondence and requests for materials should be addressed to Garrett S. Booth.