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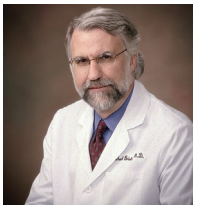

Changing the Research Culture in the United States

Christopher M. O'Connor, MD, *Editor-in-Chief, JACC: Heart Failure*,[a]
Michael R. Bristow, MD, PhD[b]

There was a time when U.S. investigators led the world in the conduct of heart failure clinical trials. The SOLVD, VHeFT, BEST, PRAISE, SCD-HeFT, ATLAS, US-Carvedilol, DIG, COMPANION, and other trials are only a short list of the many previous contributions of the therapeutic development led by U.S. investigators. Over the past decade, however, our culture has changed. The ability to spend time conducting clinical research, particularly site-based research, has diminished. The pressure to produce relative value units (RVUs), see more patients, and account for time has become greater. The introduction of the electronic health record has added hours to every clinic day. Sponsors have continued to optimize budgets and site payments, and study coordinators are under increasing pressure in a difficult regulatory environment, resulting in constant turnover due to job dissatisfaction.

In contrast, the rest of the world has rewarded investigators who conduct site-based research of high value and high performance. The economic rewards remain high, the regulatory environment is less restrictive, and the academic credit remains large. To no surprise, innovative developers and companies developing novel therapeutic agents, devices, and diagnostic tests have moved overseas to conduct their clinical research. These economic forces have continued to erode the culture of clinical research in the heart failure arena in the United States. Recruitment rates have continued to diminish on average, and a number of U.S. sites and investigators have folded their tents and moved beyond site-based clinical research.

What can be done to change this course? In an effort to identify these barriers and improve the value and efficiency of U.S. heart failure site-based research; the Heart Failure Collaboratory was formed, and has begun to address the issues to better performance (1). One of those barriers has been identified as research culture. How do we change the culture of conducting research while providing high value and high volume clinical care? It is clear that we have to begin educating and training at the fellowship level. To no surprise, site-based research that includes involvement in clinical trials is considered a low-priority research effort at many fellowship training programs. It is much easier to be involved in outcomes research, which typically includes access to established databases in which academic output is easier to obtain than in the site-based research arena. The faculty members who lead site-based research are often not in a position to routinely develop manuscripts and publications for their fellows to learn and prosper from. What are the solutions?

- Fellowship programs. We should ask that programs include a minimum of 6 months devoted to learning, participating, and conducting site-based research, including clinical research hypothesis testing and/or participating in clinical trials. It is the workforce of the future that we will need in conjunction with our clinical care to develop the never-ending number of new molecules, therapeutic targets, devices, and diagnostics that will improve the care of our patients.
- Investigators. We have to reward investigators for participating in clinical research. At a pilot program at our institution, we are acknowledging a quantitative amount of 4 RVUs for screening time and recruitment of patients into a clinical trial. This

From the [a]American College of Cardiology, Washington, DC; and the [b]Division of Cardiology, University of Colorado Anschutz Medical Campus, Aurora, Colorado.

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credit is used for educational and research grants through a $50/RVU conversion into an academic discretionary fund. We recognize that screening and identifying patients for clinical trials takes time and effort beyond the busy clinical schedule. It is through this reward structure that we can put site-based research on a level playing field.

- Study coordinators. We have to find a way to reward our study coordinators, a prized and important part of the clinical trial work force who drive clinical trial recruitment and quality assurance. This includes promotion ladders; economic and professional enhancement, which should include bonuses for exceptional performance; and retention strategies. We must find a way to do this without violating ethical contracts with our patients. By rewarding those who put in the greatest effort in screening and identifying patients for the clinical protocols through a monetary credit toward education and continuing medical education, study coordinators can gain educational credit through recruitment.
- Academic credit. It is imperative that our academic health centers look for participation by site investigators as a mechanism for academic reward, promotion, and eventual tenure. Site-based investigators of high success have achieved these milestones in Europe and other parts of the world. We have to find a way to promote this reward in the United States as well.

We have shown that research conducted in the United States has excellent quality, high expectations, and rigorous oversight. We have to find a way to evoke a cultural transformation that leads to a greater degree of enthusiasm for participation in site-based research, because our patients expect and deserve the very best care that progress and innovation can provide.

ADDRESS FOR CORRESPONDENCE: Dr. Christopher M. O'Connor, Editor-in-Chief, *JACC: Heart Failure*, American College of Cardiology, Heart House, 2400 N Street NW, Washington, DC 20037. E-mail: jacchf@acc.org.

REFERENCE

1. O'Connor CM, Psotka MA, Fiuzat M, et al. Improving heart failure therapeutics development in the United States: The Heart Failure Collaboratory. J Am Coll Cardiol 2018;71:443–53.