

tations of our data sets, we were not able to stratify our results according to race.

Robinson and Upchurch raised some methodological concerns with respect to our study in their Invited Commentary.<sup>3</sup> First, they were concerned that patients in the control group may have had a longer-standing diagnosis of PAD compared with the risk-reduction group, which can potentially confound our results. To clarify, patients in the risk-reduction group did not necessarily receive a first-time diagnosis of PAD between 2004 and 2007 as Robinson and Upchurch<sup>3</sup> suggest; patients with a history of symptomatic PAD of variable duration were enrolled in the risk-reduction program between 2004 and 2007 after vascular surgeons established eligibility. Some patients were enrolled on the basis of a previous PAD-related intervention, whereas others were enrolled on the basis of symptoms. Similarly, we established the control cohort on the basis of a visit with a vascular surgeon during the same time period (2004-2007) and a previous diagnosis of PAD within 3 years using a validated coding algorithm.<sup>4</sup> This careful approach allowed us to minimize selection bias when establishing our cohorts.

Robinson and Upchurch<sup>3</sup> also expressed concern about the comparability of the 2 cohorts in our study<sup>1</sup> owing to a lack of data about PAD severity. We established broad inclusion criteria to capture patients with varying severity of symptomatic PAD in both cohorts to increase the external validity of our study. Furthermore, it is important to note that although the natural history of patients with claudication and critical limb ischemia differ, guideline-based risk-reduction recommendations for all patients with symptomatic PAD are identical, regardless of disease severity.<sup>5,6</sup> Therefore, we believe our results are broadly generalizable to the patients with symptomatic PAD seen at vascular clinics.

**Mohamad A. Hussain, MD**

**Mohammed Al-Omran, MD, MSc**

**Thomas F. Lindsay, MDCM, MSc**

**Author Affiliations:** Department of Surgery, University of Toronto, Toronto, Ontario, Canada (Hussain, Al-Omran, Lindsay); Division of Vascular Surgery, Li Ka Shing Knowledge Institute of St. Michael's Hospital, Toronto, Ontario, Canada (Al-Omran); King Saud University-Li Ka Shing Collaborative Research Program and Department of Surgery, King Saud University, Riyadh, Saudi Arabia (Al-Omran); Division of Vascular Surgery, Peter Munk Cardiac Centre, University Health Network, Toronto, Ontario, Canada (Lindsay).

**Corresponding Author:** Thomas F. Lindsay, MDCM, MSc, Division of Vascular Surgery, Peter Munk Cardiac Centre, University Health Network, Toronto General Hospital, 200 Elizabeth St, 6EN228, Toronto, ON M5G 2C4, Canada (thomas.lindsay@uhn.ca).

**Published Online:** August 3, 2016. doi:10.1001/jamasurg.2016.2260.

**Conflict of Interest Disclosures:** None reported.

- Hussain MA, Al-Omran M, Mamdani M, et al. Efficacy of a guideline-recommended risk-reduction program to improve cardiovascular and limb outcomes in patients with peripheral arterial disease [published online April 6, 2016]. *JAMA Surg*. doi:10.1001/jamasurg.2016.0415.
- Hozawa A, Folsom AR, Sharrett AR, Chambless LE. Absolute and attributable risks of cardiovascular disease incidence in relation to optimal and borderline risk factors: comparison of African American with white subjects—Atherosclerosis Risk in Communities Study. *Arch Intern Med*. 2007;167(6):573-579.
- Robinson WP, Upchurch GR Jr. A risk-reduction program for patients with peripheral arterial disease: who benefits and why? [published online April 6, 2016]. *JAMA Surg*. doi:10.1001/jamasurg.2016.0471.

4. Fan J, Arruda-Olson AM, Leibson CL, et al. Billing code algorithms to identify cases of peripheral artery disease from administrative data. *J Am Med Inform Assoc*. 2013;20(e2):e349-e354.

5. Anderson JL, Halperin JL, Albert NM, et al. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013;127(13):1425-1443.

6. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FGR; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg*. 2007;45(1)(suppl 5):S5-S67.

## Resolving Misconceptions About Liver Allocation and Redistricting Methodology

**To the Editor** In their Viewpoint,<sup>1</sup> Ladner and Mehrotra criticize the methods used to develop a redistricting solution to geographic inequity in the allocation of deceased donor livers for transplant, and the ability of clinicians on the Organ Procurement and Transplantation Network (OPTN) Liver Committee to evaluate conceptualized changes to allocation. Their Viewpoint<sup>1</sup> contains inaccuracies about the current allocation model and the redistricting concept.

The authors write that “[i]f the mechanism of districting were sufficient to address the problem of geographic disparity, the geographic disparity between the DSAs within the same UNOS region would not exist today.”<sup>1(p110)</sup> This incorrectly presumes that livers are shared fully within OPTN regions. However, the primary allocation unit is not the OPTN region but the donation service area (DSA). Livers are offered region-wide initially only for patients listed as Status 1 or with a Model for End-stage Liver Disease (MELD) score of 35 or higher, representing only 30% of transplants performed (E. Edwards, United Network for Organ Sharing [UNOS], written communication, March 2016). Disparities between DSAs in the same region reflect local-first allocation. The criticism that redistricting “has no mechanism to address geographic disparities occurring across districts”<sup>1(p110)</sup> is invalid. The proposed districts are designed with the primary goal of reducing disparities both within and between them.

The authors incorrectly state that the models did not take into account calculated MELD and MELD exception points, but both were modeled. They further incorrectly state that most patients undergo liver transplant based on exception points, but only about 40% of transplants are performed for patients with MELD exception points.<sup>2</sup> The statement that “the MELD score was never modeled nor validated as a metric to solve disparity”<sup>1(p110)</sup> is irrelevant. Candidates with the highest MELD scores are prioritized by the allocation system; thus, disparities in MELD scores at transplant measure the extent to which geographic units distort the intended prioritization. The MELD score at transplant is one of several metrics demonstrating reduced disparity, but the district design is based only on liver supply and demand.

The authors say that “multiple solutions should be evaluated simultaneously”<sup>1(p110)</sup>; however, 27 different variants have been analyzed. The authors call for peer review; however, the redistricting models have been detailed in 6 peer-reviewed articles to date. The authors criticize the omission of a “self-correcting mechanism” for adapting to new disparities; however, the OPTN employs a rigorous self-correction process by which policy changes are studied and modifications are often made.

Current allocation policy does not comport with the Final Rule,<sup>3</sup> and the OPTN is responsible for resolving this. The authors cite no studies detailing alternative schemes that could reduce geographic disparities more effectively than redistricting, whereas all of the OPTN concepts under discussion would reduce disparities. Action is essential, and continuing the current policy will result in more potentially preventable deaths.

**Sommer E. Gentry, PhD**  
**Ryutaro Hirose, MD**  
**David Mulligan, MD**

**Author Affiliations:** Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland (Gentry); Department of Mathematics, US Naval Academy, Annapolis, Maryland (Gentry); Scientific Registry of Transplant Recipients, Minneapolis Medical Research Foundation, Minneapolis, Minnesota (Gentry); Department of Surgery, University of California, San Francisco (Hirose); Department of Surgery, Yale University School of Medicine, New Haven, Connecticut (Mulligan).

**Corresponding Author:** Sommer E. Gentry, PhD, Department of Mathematics, US Naval Academy, 572-C Holloway Rd, Mailstop 9E, Annapolis, MD 21402 ([gentry@usna.edu](mailto:gentry@usna.edu)).

**Published Online:** June 22, 2016. doi:10.1001/jamasurg.2016.1315.

**Conflict of Interest Disclosures:** Dr Gentry is a funded investigator with the Scientific Registry of Transplant Recipients. No other disclosures were reported.

1. Ladner DP, Mehrotra S. Methodological challenges in solving geographic disparity in liver allocation. *JAMA Surg*. 2016;151(2):109-110.
2. Kim WR, Lake JR, Smith JM, et al. Liver. *Am J Transplant*. 2016;16(suppl 2):69-98.
3. Electronic Code of Federal Regulations. Public Health Service, Department of Health and Human Services. Final rule. US Government Publishing Office website. [http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr121\\_main\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr121_main_02.tpl). Accessed March 3, 2016.

**In Reply** We appreciate the comments of Gentry et al in response to our published Viewpoint outlining the methodological shortcomings of the proposed “redistricting” model to solve geographic disparity in liver allocation.

In response to our critique that the model “has no mechanism to address geographic disparity occurring across districts,” Gentry et al respond that “[t]he proposed districts are designed with the primary goal of reducing disparities both within and between them.” Unfortunately, if this is true, this highlights a concerning lack of transparency. The published, deterministic optimization model that is used to determine the proposed solution includes numerous assumptions but no element for reducing disparity within a district. In fact, at the fundamental design level, the (re)districting solution is flawed in that it is incapable of responding to significant changes in organ demand across districts. We strongly believe, given the public funding of the Scientific Registry of Transplant Recipients (SRTR), that the entire model (the mathematical equations, not just select outputs) should be made publicly available in real time to allow for such an assertion to be externally tested and verified.

Gentry et al state that “only about 40% of transplants are performed for patients with MELD exception points,” acknowledging that the model does not account for a large portion of the transplants, when informing the “redistricting” design for liver supply and demand. Omitting 40% of recipients, when creating input data for a future model, is concerning and

remains unaddressed. Our own efforts replicating the current redistricting model reveal that the formed districts are very sensitive to changes in demand, and they change significantly when alternative approaches to estimate demand are applied or when data from different years are used. This “brittleness” of the proposed redistricting solution is of great concern.

In response to our critique that “multiple solutions should be evaluated simultaneously,” Gentry et al state that “27 different variants have been analyzed.” This may be true. However, the data should be publicly available for review. Our critique was specifically directed at the variants all being from within the theme of “redistricting,” rather than considering other themes (eg, concentric circles).

Unfortunately, the authors do not respond to most of our major critiques, including that (1) the SRTR ignores parameters of uncertainty and treats them as fixed deterministic values, which makes the solutions very sensitive to parameter uncertainty (eg, changes in demand/supply and waitlist behavior); (2) all assumptions are based on only 1 year (2010) of data, which are not representative of the decade; (3) no external (outside of the SRTR) methodological review or validation has been performed; and (4) the detailed mathematical models are not publicly available.

Both the transplant and scientific communities should be concerned by the unwillingness of Gentry et al to accept any critique of their methodological approach, even though these are deeply rooted in, and supported by, robust scientific arguments. Well-informed methodological concerns will not go away, and hence the SRTR should respond to these in kind and avoid potential erosion in the public trust in a joint effort to mitigate the problem of geographic disparity expeditiously.

**Daniela P. Ladner, MD, MPH**  
**Sanjay Mehrotra, PhD**

**Author Affiliations:** Northwestern University Transplant Outcomes Research Collaborative, Comprehensive Transplant Center, Feinberg School of Medicine, Northwestern University, Chicago, Illinois (Ladner, Mehrotra); Department of Industrial Engineering and Management Sciences, McCormick School of Engineering, Northwestern University, Evanston, Illinois (Mehrotra).

**Corresponding Author:** Daniela P. Ladner, MD, MPH, Northwestern University Transplant Outcomes Research Collaborative, Comprehensive Transplant Center, Feinberg School of Medicine, Northwestern University, 676 N St Clair St, Ste 1900, Chicago, IL 60611 ([dladner@nm.org](mailto:dladner@nm.org)).

**Published Online:** June 22, 2016. doi:10.1001/jamasurg.2016.1318.

**Conflict of Interest Disclosures:** None reported.

## CORRECTION

**Incorrect Figure Caption:** In the Original Investigation titled “Effectiveness of a Medical vs Revascularization Intervention for Intermittent Leg Claudication Based on Patient-Reported Outcomes,”<sup>1</sup> published in this issue of *JAMA Surgery*, an error occurred in the caption for Figure 1. The caption, which read: “Shown are the numbers of patients from baseline to 6 months.” should be replaced with “Shown are the numbers of patients from baseline to 12 months.” This article was corrected online and in print.

1. Devine EB, Alfonso-Cristancho R, Yanez ND, et al; Comparative Effectiveness Research Translation Network (CERTAIN) Collaborative. Effectiveness of a medical vs revascularization intervention for intermittent leg claudication based on patient-reported outcomes [published online August 17, 2016]. *JAMA Surg*. doi:10.1001/jamasurg.2016.2024