COMMENTARY

New Liver Allocation Policy: Flawed Moral and Empirical Foundations

Prabhakar Baliga and Robert M. Sade

On December 3, 2018, the Board of Directors of the Organ Procurement and Transplantation Network (OPTN) adopted a new policy for liver allocation that expunges and replaces principles and logistics of organ allocation policies that had operated successfully for over three decades.[1] A major underlying premise of this policy has been that the geographic boundaries of OPTN-designated Donor Specific Areas and Regions are arbitrary. MacKay and Fitz effectively demonstrate that those geographic boundaries are far from morally arbitrary;[2] rather, they are functionally relevant because of other contingent factors related to such issues as travel time that increases cold ischemic damage to organs, air travel replacing less expensive ground travel for both organs and organ recovery teams resulting in increased transportation costs, and diminished organ procurement organization (OPO) effectiveness related to impaired collaboration between OPOs and local transplant centers, which would no longer have a vested interest in maximizing organ recovery that does not benefit their local patients.

We agree that donated organs are a national resource and allocation based purely on geographic restrictions is unacceptable. The Final Rule, however, contains language that suggests organ allocation requires interplay of highly complex issues:

> Such allocation policies:
> - Shall be based on sound medical judgment;
> - Shall seek to achieve the best use of donated organs ...
> - Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement.[3]

Providing an ethical perspective, the American Medical Association Code of Medical Ethics emphasizes several ethically appropriate criteria for the allocation of limited health care resources, including likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and the amount of resources required for successful treatment.[4] None of these important issues is adequately addressed by the new policy.

In disregard of the requirements and guidelines described above, the new policy utilizes waitlist mortality as the primary metric to justify disruptive change, and the only metric applied for gaining access to organs is severity of liver disease as determined by the Model for End Stage Liver Disease (MELD) score. The waitlist mortality metric is an inadequate mea-

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sure to determine allocation, in part because it does not include patients who were removed from the list; patients are removed usually because they become too sick to transplant, then die after removal from the list — they should be included among the dead. Moreover, some MELD scores have been inflated by physician-designated exceptions that are widely variable across regions, further confounding the policy's rationale.

Other measures that impact patient outcomes were also not considered in the new proposal, such as Community Health Scores; low scores reduce access to care and are associated with increased waitlist mortality.[5] Fewer patients with liver disease are added to the donor waiting list in communities that are rural, of low-socioeconomic status, or composed mainly of racial or ethnic minorities. Because of other social determinants of health, transplants and deaths on the waitlist tend to occur at lower MELD scores. For these reasons, the waitlist mortality in South Carolina is fivefold higher than in New York and Massachusetts. This imbalance will be magnified by the shift of allocated livers to the Northeast and will further exacerbate South Carolina mortality.

The definitions and models underlying the statistical basis of the new allocation policy do not have wide support in the transplant and epidemiological communities, because modeling predictions and real time observations have been notoriously inaccurate. Indeed, the only real experiences with geographically broad sharing have failed to show benefit.[6] While MacKay and Fitz persuasively demonstrated that geographic boundaries are clearly not arbitrary, what is arbitrary is allocation based on a MELD score of 29 in the new policy, as are the distances of 250 and 500 nautical miles.

The potential impact of the new policy is unknown, but organ donation seems likely to diminish when local communities discover that their donated organs are being sent to large, relatively wealthy urban populations. Moreover, the number of successful transplants may decline because of organ damage resulting from the logistics of travel and liver preservation. These undetermined effects make it difficult to justify the radical and divisive change in allocation that the new policy represents.

The UNOS Board's adoption of the new policy may have been partly in response to a threat of legal action by a few transplant centers in the face of an extremely short timeline mandated by the Secretary of the Department of Health and Human Services (DHHS), who manages the OPTN contract.[7] In fact, the geographic controversy in liver allocation is not new and has been politically driven since 1996, when the Secretary of DHHS proposed a single national list. This proposal led to considerable turmoil in the transplant community. The US Congress subsequently asked the Institute of Medicine (now called the National Academies of Science, Engineering, and Medicine) to consider the issue. Their conclusion supported broader sharing, but several caveats were similar to those we have cited, including the need to consider organ utilization (cold ischemic time), costs, and specifically "sharing arrangements among organ procurement organizations to avoid disrupting effective current procurement activities."[8]

As we write this commentary in early 2019, the new policy has been adopted by the OPTN Board and is scheduled to become effective in April 2019. Efforts are currently being marshaled to block its implementation with lawsuits from regions of the country that

In conclusion, the organizational framework for organ donation and transplantation has been successful in providing positive outcomes of solid organ transplantation for over three decades, yet the system has been made precarious because of a new allocation policy that is divisive and may prove to be counterproductive in the context of the OPTN's goals of efficient and fair organ allocation. Rather than disputes over how to divide the slices of a limited and fixed pie, the focus should have been and in the future should be on maximizing organ donation and utilization. In our opinion, the best way to achieve this goal would be within the system that was developed over several decades with great care in the context of broad deliberation and consensus-building.

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will be severely harmed by the new policy. In addition, new legislation has been submitted to Congress to amend the National Organ Transplantation Act of 1984 (NOTA) to enforce a more rational approach to organ allocation.[9] At this time we cannot know for certain how the policy terrain will be configured several months from now, but dissatisfaction, unrest, and hostility will surely perturb the transplant community for some time to come.

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