ASN
American Society of Nephrology

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Massachusetts General Hospital
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RE: Concepts for a Collaborative Approach to Living Donor Data Collection

Dear Dr. Rudow and Dr. Elias:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to respond to provide comment regarding the Organ Procurement and Transplantation Network (OPTN) concept paper “Concepts for a Collaborative Approach to Living Donor Data Collection.”

ASN commends the Living Donor Committee and OPTN for their work to conceptualize a future state of living donor data collection. The society strongly supports the ideas laid out in this concept paper, including requiring collection and reporting of living donor candidate and donation decision data, sharing that data with the Living Donor Collective, enabling the Living Donor Collective to directly follow-up with living donor candidates and living donors long-term on a national level.

Enabling the use of more organs to allow more patients to receive a transplant, including by better supporting living donors and mitigating the barriers they must overcome to successfully donate, is a top ASN policy goal. The vision articulated in this concept paper advances this objective on several levels, particularly by helping us to understand, monitor, and better meet the needs of both potential and actual living donors. As noted, while the benefits of living donation to recipients are well-documented, a more comprehensive understanding of the implications of living donation in the short- and long-term would fill knowledge gaps to better inform the decision-making process for individuals considering living donation.

Additionally, these data could, among other things, help researchers understand how to narrow the gap between the number of potentially interested living donors and actual living donors, providing inferences on how to address barriers to donation. While living donation is generally regarded as safe, the committee presents ample evidence that current living donor follow-up practices do not provide sufficient data to understand long-term outcomes. The Living Donor Collective, established as a long-term follow-up pilot in 2016 by the Scientific Registry of Transplant Recipients (SRTR), has proven to be an effective model. Its success should be leveraged and expanded upon on a nationwide basis, as suggested in this concept paper.

Definitions

ASN supports the committee's recommendation to define a living donor candidate as "an individual who was seen at a transplant program for evaluation." The society appreciates the committee's presentation of alternative approaches to this definition but agrees with the conclusion that this approach would provide a balance between meaningful data collection and data collection burden and would capture a group of individuals who are sufficiently invested in the process and may be more likely to engage in long-term follow-up, regardless of whether they proceeded with donation or not. This consideration is important given the objective of creating a comparator group other than the general population to serve as a control group against which to compare outcomes of living donors.

ASN strongly supports the Committee's goal to maintain a single integrated approach in which there would be no redundancy in data entry across OPTN and SRTR multiple systems.

Data elements to collect

A key goal of this effort is to generate a dataset that helps researchers, health professionals, and policymakers identify impediments to living donation that can potentially be addressed through policy change. Moreover, collecting information regarding barriers to donation can help us understand and bridge barriers that contribute to disparities in living donation along socioeconomic, geographic, and other lines. Accordingly, ASN supports the collection of robust demographic information to identify such potential barriers. ASN appreciates the committee's inclination to collect the minimum essential data, but suggests that the collection of some element of socioeconomic status (or the ability to infer it with reasonable accuracy, such as based on ZIP code+4), and the candidate's perception as to whether donation may present a financial hardship be prioritized.

This data could also help inform efforts to ensure appropriate funding for entities that provide financial assistance to cover the costs of living donation, such as through Congressional support for the National Living Donor Assistance Center. Similarly, ASN recommends consideration of a more specific question about whether candidates have the ability to take leave (paid or unpaid) from work, which would be invaluable in helping understand (and eventually address) barriers to donation for different types of employed individuals. Related, as the committee notes, insurance status is another element potentially affecting candidates' ultimate ability to donate about which little is known.

Some ASN members report that barriers to donation arise when one family member wishes to donate to another, but that potential living donor is also the best-positioned (or only possible) member of the recipient's network to provide post-operative care. While the Living Donor Collective wouldn't be in the position of resolving the dilemma of lack of post-operative support within a family or social network for both recipient and living donor, asking donor candidates a question about availability of post-operative care could help us learn more about it and potentially point to future policy solutions.

The society notes that the crosswalk provided in Appendix A stipulates that "Additionally, all data elements in the table are required data elements." ASN recommends that any data fields for which collected through the Living Donor Collective be mandatory: if only a subset of programs complete these fields, it becomes very to make meaningful comparisons based on a patchwork of data.

Data collection responsibility
ASN supports the concept of requiring transplant programs to report donation decisions and reasons why for all living donor candidates to the OPTN, with the goal of creating a national understanding of access and barriers to living organ donation. This universal requirement would lay the foundation that would allow the Living Donor Collective to take on long-term follow-up of living donor candidates and living donors at a national level. Current OPTN policy requires that the Living Donor Registration (LDR) form be completed by the transplant center at 6-, 12-, and 24-month intervals.

ASN also believes the rationale presented for shifting the burden of data collection for 12- and 24-month follow-up from transplant centers to the Living Donor Collective makes sense, particularly in terms of balancing the reporting burden on transplant centers as they are (if the concept is eventually finalized) required to report donation decisions and reasons why for all living donor candidates. As the committee lays out, evidence suggests there are several reasons why transplant programs may not be the best vehicles for collecting these data long-term, including that living donors may not be local to the transplant program because they either traveled for donation or moved post-donation, or because financial coverage of the follow-up appointments may be an additional barrier. With the OPTN registering living donor candidates, it would allow the Living Donor Collective to pivot resources to support the shift in 12- and 24-month follow-up data collection and beyond.

Engaging with living donors
ASN commends the committee for its emphasis on engaging living donors themselves to provide their feedback on how they seek to engage in long-term follow-up. ASN concurs that the data elements that health professionals find valuable may diverge from those living donors themselves are interested in, and seeking their input is imperative.

In sum, ASN appreciates OPTN's and the committee's effort to seek early input from the community on practical approaches to collecting longitudinal living donor data on a national level. The society strongly supports these efforts and looks forward to additional updates and opportunities to provide feedback on this important endeavor. Please contact ASN Strategic Policy Advisor Rachel Meyer at rmeyer@asn-online.org with any questions or to discuss this letter in more detail.

Sincerely,

Michelle Josephson

Michelle A. Josephson, MD, FASN
President