Personal Viewpoint

Engaging Living Kidney Donors in a New Paradigm of Postdonation Care

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Recent studies have highlighted the need for better understanding of the long-term health outcomes of living donors. Barriers to establishment of a dedicated long-term donor follow-up data system in the United States include infrastructure costs and donor retention. We propose providing all previous and future living donors with a lifelong health insurance benefit for the primary purpose of facilitating acquisition of health information after donation as an alternative to establishment of a dedicated donor follow-up data system. Donors would consent to allow collection and analysis of their medical data, and continuation of insurance coverage would require completion of regular health assessments. The extension of health insurance would be analogous to the established practice of paying people for participation in a research study and would provide a mechanism to engage donors in a new paradigm of postdonation care in which donors are actively involved in their own health maintenance. Rather than acting as an inducement for donation, providing donors with the ability to easily contribute information about their health status represents a practical strategy to acquire the long-term medical information necessary to better inform future generations of living kidney donors.

Abbreviations: ESRD, end-stage renal disease; NOTA, National Organ Transplant Act; OPTN, Organ Procurement and Transplantation Network

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Living kidney donors volunteer to undergo a complex medical and surgical procedure that poses physical, psychological and financial risks with no direct medical benefit to themselves. The medical community has a long-standing interest in understanding the risks of living kidney donation, and recent information has highlighted the limitations of our knowledge. Specifically, in contrast to the well-documented surgical risks, our understanding of the long-term medical consequences of living donation remains incomplete. Although these risks may be small, this knowledge gap may deter future donors; preclude acceptance of donors who may be at higher risk, including black donors; and undermine the trust of previous donors. As such, this knowledge deficit represents a threat to the future of living kidney donation, and a concerted plan to address this deficiency is needed. In this viewpoint, we advance a proposal—endorsed by the American Society of Transplantation board of directors—to address this urgent information need.

Uncertainty About the Long-Term Risk of Donation

Information about the long-term outcomes of living kidney donors was initially derived from single-center studies that compared outcomes, including survival and end-stage renal disease (ESRD), between donors and the general population (1–5). Reassuringly, these studies reported that donors had similar or better outcomes—an expected result, given the careful selection of living donors. The largest of these studies in the United States was limited by the inclusion of primarily white donors who donated in an era when conditions such as hypertension and obesity were less common and usually were exclusions for donation (2). Subsequent work confirmed a lower risk of death and cardiovascular disease in donors compared with healthy persons in the general population who may have been suitable to donate (6–8). Two recent studies, however, reported an increased risk of ESRD in donors compared with control groups derived from healthy participants in unrelated epidemiological studies (9,10). Although the absolute risks of ESRD were low and the appropriateness of the control groups examined has been challenged (11,12), these studies highlighted the need for better understanding of the long-term health outcomes of living donors, especially because the median postdonation follow-up in the US study was <8 years (9).

In our opinion, the focus of future data-capture initiatives should be understanding the natural history of health status changes in donors and identifying opportunities to prevent development of serious complications such as ESRD rather
than attempting to determine the attributable risks of donation. Ascertainment of the attributable risk of donation will always be limited by the observational nature of the information and may be misleading to potential donors when the absolute risks are low (11,13).

Strengths and Limitations of Donor Information in the United States

The United States maintains the world’s leading data system for transplant recipients. The system is enabled by mandatory reporting of information to the Organ Procurement and Transplantation Network (OPTN). A similar approach for living donors is not feasible because, lacking a recognized chronic disease, donors are not considered to be patients and thus are not subject to long-term follow-up. The need for a dedicated donor follow-up system is somewhat particular to the United States. In most developed countries, living donors are included in government-funded health insurance programs that enable the collection of longitudinal health information after donation. The absence of a similar system in the United States is a long-standing disadvantage compared with other nations. The creation of a durable solution is required to maintain confidence in the living donor system.

The mandated reporting of all living kidney donations to OPTN allows for rigorous ascertainment of the sentinel events of ESRD and death after donation by linkage to the Center of Medicare and Medicaid Services medical evidence Form 2728 and the Social Security Death Master File. Notwithstanding the strengths of this system, the approach fails to capture information about nonsentinel events, including hypertension, diabetes, obesity, cardiovascular disease, acute kidney injury and autoimmune disease, that may be important risk factors for ESRD in donors. The isolated capture of ESRD events in donors without understanding the factors contributing to these outcomes may lead to erroneous conclusions regarding the risks of living donation.

Given that ESRD is a rare outcome and that the time interval between donation and events is long, dedicated donor follow-up studies will be costly, logistically challenging and likely of limited use in advancing understanding of chronic kidney disease after living donation. Although targeted follow-up studies in at-risk groups (e.g. those with preexisting risk factors such as hypertension and obesity) may be more feasible, it is likely that these approaches would still be prone to selection and follow-up bias.

Development of a new data-capture strategy requires critical assessment of the value of existing processes. The recent requirement to submit information about living donors to OPTN at the time of hospital discharge and at 6, 12 and 24 months following donation does not address a significant knowledge void, deflects resources away from initiatives to inform long-term risk and may provide a false sense of security about the safety of living donation by focusing on short-term outcomes. The transplant community, government and society have a responsibility to advocate for living donor medical follow-up and study over a clinically meaningful time frame.

Proposal for a New Data System

The Advisory Committee on Organ Transplantation encouraged the Secretary of the U.S. Department of Health and Human Services to mandate that data on the general health status of living donors be collected on a nationwide basis by a centralized entity for a period of 10 years following donation (14). This recommendation and initiatives like it have stalled primarily because of issues related to cost and funding. The major expense related to such an initiative would be the creation of infrastructure to support mandatory donor follow-up. These costs could be minimized by enlisting donors as partners and providing them with the ability to easily contribute information about their health status. Accordingly, we propose providing all previous and future living donors with a lifelong health insurance benefit for the primary purpose of facilitating acquisition of health information after donation. Previous donors would complete a standardized baseline health status assessment and laboratory investigations at the time of consenting to join the program. Prospective living donors would consent to allow the collection and analysis of their medical data at the time of donation. Prospective donors who do not consent to the program could still donate but would not receive the health insurance benefit. Continuation of insurance coverage would require completion of regular health assessments. The number of existing and prospective donors who did not participate in the program or who withdrew after donation would be captured, and only the sentinel events of death and ESRD could be determined for these donors through existing data-capture mechanisms.

This approach is supported by the literature: The best information regarding changes in health status after donation has been derived from studies in donors with health insurance (15). The well-known limitations of billing claims include the fact that claims are insensitive to clinically silent changes in health status such as kidney function and proteinuria and are subject to incomplete follow-up due to changes in insurance coverage. Such limitations would be minimized by the provision of a lifelong mechanism for donors to undergo regular laboratory testing and by the requirement for donors to complete a limited number of essential tests (e.g. measurement of kidney function, blood pressure, body mass index, screening for diabetes and proteinuria) longitudinally to maintain insurance coverage. The requirement for submission of health information in exchange for a health insurance benefit is not unique to our proposal. Enrollment in the ESRD Medicare
program, for example, requires submission of health information both at the time of first treatment and longitudinally.

The extension of health insurance would also provide a mechanism to enlist donors in a new program of post-donation care that would engage donors in their own health maintenance, facilitate understanding of changes in their health status and promote appropriate use of health resources. Insurance could be provided through a single provider such as Medicare, or the program could pay the premiums for donors to continue coverage with their existing insurer as long as the insurance provider was able to submit donor claims and information from the longitudinal health assessments to the program. The program would represent a paradigm shift in living donor follow-up consistent with the advancement of patient-centered care initiatives, which have demonstrated improvements in the quality of care in a variety of health care settings (16).

To achieve this objective, we envision providing donors with access to their laboratory results and health information in a format that facilitates understanding of how their results compare with those of other donors. This would be complemented by development of tailored educational materials to promote donor health and to share new insights informed by the contribution of donor health information. Ideally, donors would complete the longitudinal health assessments in the transplant center at which they donated, but donors would also be able to complete the health assessments with their primary care provider to minimize the burden of follow-up. Donors would also have the opportunity to pose questions to transplant experts and to provide input to improve the delivery of living donor services before and after donation. Finally, researchers would be able to identify and consent donors for participation in other studies through the program. Development and implementation of the program would require donor and multidisciplinary input. The success of the program would in part depend on ongoing donor engagement and assessment of donor acceptance of the program, particularly the responsibility for donor follow-up and completion of longitudinal health assessments to maintain the health insurance benefit.

A similar approach has been used in Vancouver, Canada. Donors receive an annual reminder to complete a blood pressure check with their primary care physician together with a requisition for a limited number of laboratory investigations. In this model, donors are encouraged to participate in their own health maintenance, and follow-up is directed through the primary care physician. Transplant center physicians are able to access the information and provide management advice to the primary care physician if required. In the Canadian system, in which there is no obligation to complete the recommended follow-up, two-thirds of the donors complete the follow-up annually, and >80% complete at least one follow-up assessment every 5 years.

The incremental costs of this proposal are limited and should be considered in comparison to the cost of alternative strategies and potential benefits to system. Donors are preselected to be healthy and should consume fewer health care resources than the general population. Less than 20% of donors are uninsured at the time of donation (17), and the additional insurance benefit for donors would be limited to the years between the age of donation and the age of 65 years, when all citizens become eligible for Medicare coverage. When the cost of alternative strategies (e.g. cohort studies or a dedicated donor registry) and potential benefits (e.g. early detection and prevention of health conditions after donation, acceptance of donors who are currently excluded from donation because of lack of health insurance) are considered, the proposal may be cost neutral or even cost saving.

Legal Considerations

Perhaps the most contentious aspect of our proposal is the potential violation of the National Organ Transplant Act (NOTA) (18). NOTA has a section outlawing the sale of organs that has been broadly interpreted as prohibiting the receipt of any valuable consideration in exchange for donating an organ for transplantation. Although the extension of health insurance in our proposal is a valuable consideration, the objective of providing this benefit is to ensure acquisition of long-term health information from donors and not to induce organ donation. In this regard, the provision of health insurance is not dissimilar to payment for participation in a traditional research study. The provision of insurance coverage for complications related to living donation is noncontentious; the Declaration of Istanbul specifically identifies the provision of insurance coverage for donation-related events as a necessary requirement (19). We assert that because the long-term risks of living donation are incompletely understood, restricting insurance coverage to donation-related events may be difficult and, in some cases, an arbitrary distinction. Furthermore, the argument that the long-term complication of renal failure is already ensured through Medicare coverage of ESRD ignores that fact that ESRD events may be preventable with timely recognition and treatment of risk factors. Although our proposal would provide insurance coverage for some medical conditions not related to donation (i.e. cancer), we do not believe these considerations would serve as significant inducement for persons who are healthy and who anticipate remaining healthy to donate a kidney in the United States.

We believe it is a moral and medical imperative to provide persons who are selflessly contributing to society, by literally giving of themselves, with accurate and relevant information necessary to make an informed decision. By enlisting donors to contribute to our understanding of the long-term risks of a medical practice that saves the health care system millions of dollars annually, our proposal...
is likely to benefit society more than individual donors. The fact that our proposal may also directly benefit donors is a byproduct that, in our opinion, does not challenge the original intent of NOTA.

Conclusion

That living donors directly help their recipients is indisputable. They also help society by reducing the economic and social costs of caring for patients with ESRD. Their inclusion in Medicare is a practical strategy to acquire their long-term medical information to better inform future generations of living kidney donors. We should make it easy for them by establishing a mechanism that not only efficiently captures their data but also enables them to maintain their health status. It is only right that we help them to help us yet again.

Disclosure

The authors of this manuscript have no conflicts of interest to disclose as described by the American Journal of Transplantation.

References