

A Conflict of Responsibility: No Patient Left Behind

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In its program END THE WAIT, the National Kidney Foundation (NKF) outlined four comprehensive strategies to achieve the goal that within 10 years, every individual on the US waiting list will receive a transplant within 1 year of listing. Lifetime immunosuppressive coverage is a critical piece of the foundation of this program. Events in 2009 that were dedicated toward achieving a lifetime immunosuppressive benefit were complicated by legislative challenges and a dynamic that placed oral medications in the ESRD bundling proposal in direct conflict with the potential for the lifetime immunosuppressive benefit. In line with its mission, the NKF could not sacrifice one kidney patient constituency for another. Successful patient-centered organizations stay consistent with their mission. The NKF had to weigh the risk of postponing a long-sought goal and its relationships with other organizations with standards of patient safety and equitable and efficient patient care. In a perfect world, we never have to make such choices. In the real world, we can use such choices to forge new ways and dialogue to achieve better health care for all patients affected by kidney disease.

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The Dynamic in Kidney Health Care, Immunosuppression, and the National Kidney Foundation

The dynamic in kidney health care that evolved during the recent debate on health care reform was passionate and spirited. A large part of that dynamic was ironically driven by the passage of the Medicare Improvement for Providers and Patients Act (MIPPA) in 2008. For the National Kidney Foundation (NKF), the MIPPA represented a set of opportunities to advocate for improved patient education and quality kidney health care. During 2009, the MIPPA and the ESRD bundling proposal incorporated within it also became an important point of evaluation for the NKF as a patient-centered organization, especially when choices related to medication coverage defined by Congress suddenly put the NKF into a potential conflict of responsibility.

The mission of the NKF is preventing kidney disease, improving the health and well-being of individuals and families affected by kidney disease, and increasing the availability of all organs for transplantation. The NKF has been a constant voice supporting ways to increase the availability of organs for transplantation and has also been a strong partner and leader in efforts to extend coverage for immunosuppressive medications for a generation.

NKF advocacy for immunosuppressive drug coverage under Medicare dates to 1984. The NKF convened a consensus conference, "Impact of Cyclosporine on Cadaveric Renal Transplantation." The NKF can be credited with the initiation of 1 year of coverage in 1986 through the Omnibus Budget Recon-

ciliation Act of 1986 (Public Law [PL] 99-509). The NKF can also be credited also with gradual extension to 3 years of coverage during the 1990s through the Omnibus Budget Reconciliation Act of 1993 (PL 103-66). The NKF aggressively supported the limited expansion of Medicare coverage in the Balanced Budget Refinement Act of 1999 (PL 106-113) and the elimination of the 3-yr window in the Benefits Improvement and Protection Act of 2000 (for individuals who are not dependent on ESRD status for Medicare coverage).

END THE WAIT and a Conflict of Responsibility

In its program END THE WAIT, the NKF outlined four comprehensive strategies to achieve the goal that within 10 years, every individual on the US waiting list will receive a transplant within 1 year of listing. Lifetime immunosuppressive coverage is a critical piece of the foundation of this program that recognizes coordinated efforts to improve the outcome of first transplants, increase deceased and living donation, and improve the capacity of the US transplant system to achieve the program's goal.

In pursuing broader immunosuppressive coverage, the NKF, in parallel with other transplant organizations, undertook collaborative efforts with the staff of Senator Richard Durbin (D-IL) and Representative David Camp (R-MI) throughout the fall of 2008 and most of 2009 to facilitate immunosuppressive medication coverage legislation. This was followed by introduction of Senate and House bills to address immunosuppression coverage in March 2009. S.565 was introduced by Senator Durbin on March 10, 2009. H.R. 1458 was introduced by Representative Camp on March 12, 2009. During 2009, the NKF presented END THE WAIT to the Transplant Roundtable and dialogued as a member of the Immunosuppressive Coalition. This was followed by introduction of Senate and House bills to address immunosuppressive medication coverage in March

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2009. Each bill was crafted with similar messages from the NKF and other influential transplant organizations, including the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) as well as the American Society of Nephrology (ASN). Indeed, the expansion of Medicare coverage was included in the health care reform bill that passed the House of Representatives (HR 3962).

The NKF then implemented its immunosuppressive coverage communication plan, potential strategies to offset the expense of an immunosuppressive benefit, and presented the END THE WAIT portfolio to Kidney Care Partners, a collaborative partnership of key kidney health care organizations, industry partners, and advocacy groups to which the NKF belongs. Kidney Care Partners itself advocated for immunosuppressive medication coverage as a priority beginning in the spring of 2009; however, a conflict of responsibility was bearing down on the NKF. Congressional staff communicated that the NKF needed to endorse changes in the oral medications to be included in the ESRD bundling proposal. Failure to do so would eliminate the possibility of immunosuppressive medication coverage. The NKF responded with correspondence in concert with the AST and the ASTS and media releases emphasizing the importance of providing immunosuppressive coverage. At the same time, the NKF had to examine the implications of the Congressional staff suggestion. The answer to the last question was \$14. Once the Centers for Medicare and Medicaid Services proposed rule regarding the ESRD bundling proposal was available for public comment, it became apparent that the available funding for medications for patients who have ESRD and are on dialysis in the bundling proposal would be \$14 per patient per treatment.

Now arose the conflict in responsibility for the NKF. The NKF remained (and remains) absolutely supportive of a lifetime immunosuppressive benefit, yet \$14 for medications for a dialysis patient per treatment without a defined set of outcome measures to assess quality of care was placing the ESRD population on dialysis at tremendous risk. To achieve expanded immunosuppressive medication coverage at the expense of safety for another kidney patient constituency placed the NKF in this conflict of responsibility. In line with its mission, the

NKF could not sacrifice one kidney patient constituency for another.

Looking at the Future

The NKF continues to support the AST, the ASTS, and the ASN as they approach transplantation health care, sometimes from very different perspectives. An example of such alignment is renewed legislative efforts this year. AST policy leadership informed the NKF of interest among Senator Durbin's staff regarding extension of immunosuppressive coverage without the binding link to the ESRD bundling proposal. The NKF signed on to AST correspondence again supporting the immunosuppressive medication coverage benefit. These efforts achieved a new piece of potential legislation: The Comprehensive Immunosuppressive Drug Coverage for Transplant Patients Act. Unfortunately, the immunosuppressive provision was not contained in the reconciliation package passed by the Senate on March 25, 2010. However, these efforts also prompted the NKF to formalize the END THE WAIT task force into an organizational committee, co-chaired by Francis Delmonico, a transplant surgeon, and William Singleton, a kidney donor. This committee has already initiated broader dialogue with transplant organizations across the United States to expand the cooperative efforts needed to make END THE WAIT a reality.

Successful patient-centered organizations stay consistent with their mission. On an issue that has been at the heart of NKF efforts for a generation, the NKF had to weigh the risk of postponing a long-sought goal and its relationships with other organizations with standards of patient safety and equitable and efficient patient care. In a perfect world, we never have to make such choices. In the real world, we can use such choices to forge new ways and dialogue to achieve better health care for all patients affected by kidney disease.

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Disclosures

B.N.B. is president of the National Kidney Foundation.