Over the past two decades, UNOS has grown from a handful of employees to a staff of hundreds. This photo—which includes many of UNOS' 300 employees—was taken in April in the Butterfly Garden of the National Donor Memorial during one of UNOS' events recognizing National Donate Life Month.

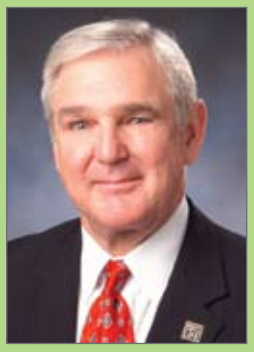
The 'Yin and Yang' of UNOS

A personal retrospective on UNOS since 2000

Editor's note: In part 1 of his retrospective, published in the May–June issue, executive director Walter Graham described UNOS' beginnings and early years. In part 2, Graham picks up where he left off and takes UNOS into the present—and future.

BY WALTER GRAHAM

The OPTN Final Rule, issued by the Department of Health and Human Services (HHS) in 2000, is *the* defining act/document of the current embodiment of the OPTN. A watershed event in UNOS' history, the issuance of the Final Rule created a new and fundamentally different OPTN from the OPTN that UNOS operated from 1986 until 2000.



Walter Graham

Even so, UNOS remained true to its philosophy of making policies by consensus through inclusion and participation. Many of the operating details of that approach, in fact, were codified in the Final Rule as the legally specified way the OPTN is to function.

The Final Rule established a new policy-development process for the OPTN and set out the basic requirements for organ allocation policies, including performance goals. The Final Rule also required that allocation performance indicators be established, moving OPTN policy-making into the realm of evidence-based medicine.

As a result of those requirements, UNOS completely revised the OPTN's organ-allocation policies for livers, hearts and lungs. The policies put in place after the Final Rule were far more complex than those that preceded it.

The resulting policies for liver allocation, known as MELD and PELD [Model for End-Stage Liver Disease (for those over 12), and Pediatric End-Stage Liver Disease model (for those 11 and younger)] achieved widespread consensus and resolved a long-standing national debate about the best way to allocate livers. The new lung allocation policy is one of the most complex and sophisticated policies the OPTN has ever developed.

Recent changes in the heart distribution policy began to address the age-old allocation issue of geographic distribution in favor of patients with the most urgent need. The change already has led to a decrease in deaths among patients awaiting heart transplantation.

All of these changes were a direct result of the Final Rule. Currently, the OPTN/UNOS kidney transplantation committee is reconsidering kidney allocation policy to ensure it adheres to the Final Rule's principles.

The Health Resources and Services Administration (HSRA) awarded UNOS a new contract in 2000 to operate the OPTN based upon the Final Rule's provisions. Among other things, the contract required routine site reviews to determine whether OPTN policies were being followed. Also included were new requirements for bringing members into compliance.

Also, in 2000 HRSA decided to award the contract for performing analysis of Scientific Registry of Transplant Recipients (SRTR) data—which supports OPTN policy development—to an organization separate from the organization holding the OPTN contract. HRSA awarded that contract to Arbor Research Collaborative for Health; HRSA kept the data collection and registry maintenance functions, however, in the OPTN contract at UNOS.

MEMBER SANCTIONS, PUBLIC SCRUTINY

Perhaps the most significant change brought by the Final Rule is the increased severity of actions the OPTN can take when members don't comply with OPTN policies. As compared with the prior era, when UNOS' authority was constrained by the fact that OPTN policies were regarded as voluntary guidance, UNOS is now under tremendous public scrutiny.

There now is significant pressure on the OPTN from the public, the media, the government (including Congress as well as HHS and HRSA) and UNOS' own members and volunteer leadership to take appropriate action, including member sanctions, when OPTN policies are not followed.

The Final Rule stipulates that the OPTN use peer review. UNOS uses confidential medical peer review in two distinct ways: to assist transplant centers with quality improvement when outcomes at a center fall below expected risk-adjusted levels; and, along with formal due process, to review potential policy violations and determine action to be taken when policies are violated.

Peer-review provides OPTN/UNOS members as well as committee participants with privacy protection during the review process. Adverse actions that result from these deliberations, however, are made public once they are finalized.

Patient safety. Since 2000, beginning with the Institute of Medicine's seminal report, *To Err is Human,* there has been a major emphasis throughout the U.S. health-care system on patient safety. The safety of transplant patients—always of critical importance—has now become a major area of additional emphasis for the OPTN.

This added emphasis on patient safety—along with the requirements of the Final Rule—has generated a sea change in expectations for OPTN operations, which UNOS continually

strives to meet. One factor that can have an impact on patient safety is the potential for increased risk or co-morbidities from older donors.

Increasingly, organ procurement organizations (OPOs) and transplant centers that violate OPTN requirements, especially when patient safety is jeopardized, can expect public reprobation—some of which, as a result of OPTN sanctions, may have negative financial results.

Living donation. In 2006, HRSA announced a new interpretation of the Final Rule, which said that the OPTN has oversight responsibility for living-donor transplantation with the concomitant authority to enforce living-donor policies with the same sanctions as those conveyed by policies for deceased-donor transplantation. UNOS' new oversight responsibility includes the safety and well-being of living donors.

Additionally, in 2007 legal impediments were removed that had prevented the OPTN from being engaged in paired donation for living-donor transplants. UNOS now is moving to implement a national policy and system for facilitating those transplants.

Because OPTN policies have such significant effects on and consequences for member organizations as well as the lives of tens of thousands, it is more important than ever that OPTN members and the interested public participate in policy development.

It is seldom possible to achieve unanimous consent. It remains possible, however, to find a broad consensus—but only if there is wide and informed participation.

With that in mind, I urge readers to participate in the discussions on policy proposals. By doing so, you will help the OPTN achieve consensus on its policies and accomplish what is truly in the best interests of the patients we serve.

The National Donor Memorial. While there have been many accomplishments for UNOS over the years, perhaps one that gives me the greatest sense of pride is the establishment of the National Donor Memorial honoring America's organ and tissue donors.

This beautiful 10,000-square-foot monument—an integral part of the UNOS headquarters building in downtown Richmond, Va.—was built entirely through private funding from thousands of financial contributors. Every day, its inspirational presence serves to remind those of us who work in the building of the reason we are here.

The words of the Memorial's logo, chosen by the design committee of donors, families and recipients from around the country, speak aptly to what transplantation is all about—hope, renewal and transformation.

Those three words—hope, renewal and transformation—explain why many of us at UNOS, myself included, are dedicated to and inspired by our work.

THE FUTURE

It has been a fantastic 21-year journey, and there are new and exciting developments on the horizon as UNOS moves into its third decade.

The new authority HRSA recently gave the OPTN in the area of living-donor transplantation is taking the OPTN in a challenging new direction. The OPTN also is rapidly moving toward becoming a high-performance health organization that can provide leadership for health care throughout the nation.

UNOS' work with the Centers for Disease Control and Prevention (CDC) in developing a Transplantation Transmission Sentinel Network (TTSN) may well expand into a major new national—and perhaps international—network for communicating among transplant organizations about disease transmission in organ, tissue and cornea transplants.

UNOS itself also is seeking to become an even more responsive membership organization that provides its members with a wide variety of services. The next 20 years in UNOS' history will see changes and improvements that cannot even be imagined today.

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