

**2008 Presidential Address
American Society of Transplant Surgeons
American Transplant Congress**

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Standing On the Shoulders

Members, colleagues and guests, I stand before you as the President of the American Society of Transplant Surgeons, which is a humbling honor that I would never have dreamt of receiving in May 1980 when I attended my first ASTS Meeting at the Drake Hotel in Chicago. To be your president is to have an enormous trust placed in me by the membership, which carries with it a responsibility to you, the ASTS members, but also to our colleagues in the American Society of Transplantation, to all non-member physicians involved in transplantation, to the transplant programs, and most of all to our patients who place their trust in us to restore them to health.

This year would not have been possible without the assistance of my family for which I am immensely grateful. I am hugely indebted to my wife Tina and my three sons, Marcus, Erik and Philip, for giving me their love and support, as well as allowing me time away from them to dedicate myself to the society.

Also, thanks to my colleagues at home, who closed ranks behind me so that I could do this job. I am sure you recognize the distinctive profiles of Robert Goldstein, Marlon Levy, Edmund Sanchez, Srinath Chinnakotla, Henry Randall, Greg McKenna, Richard Ruiz, and Nick Onaca.

My predecessor, Art Matas, here seen with Sandy, Tina and I at the Winter Symposium last January, told me after I received the gavel last year to start working on my presidential address right away. That was very good advice. Over the next thirty minutes I will share a few of the multitude of issues that not only ASTS, but the entire society of transplantation will face in the not so distant future.

The three issues I will address are:

1. How We Got Here
2. Regulatory Oversight
3. The Future of Transplantation

I will begin with how we got to where we are.

My first mentor was Carl Groth at the Karolinska Institute in Stockholm, who gave me a solid platform in transplant surgery, you see Carl here at the helm. When he attended the ASTS meeting at the Drake in 1979, he “sold me” to Tom Starzl. The slave trade did not cease with the end of the Civil War. This is how I found myself at my first ASTS meeting...

My first ASTS meeting was in Chicago at the esteemed Drake Hotel in May 1980. As a transplant fellow in Denver I was there with my second mentor, Thomas Starzl. It was an awe inspiring event - one single session where every abstract was presented and discussed by all the attendees.

All the pioneers in transplantation were there: Medawar, Starzl, Calne, Pichlmayr, Hume, Belzer, Carrel, Najarian, Murray, Bismuth, and Cooper to mention a few. The discussion was lively and insightful. Topics on the floor included the effect of transfusion on renal allograft survival, HLA matching, ALG, and surgical innovations. The corridors were buzzing about Roy Calne's mystery drug, Cyclosporine A, which at this time, only a handful of individuals in the U.S. had used. In Denver, we had started using it 6 months earlier in December 1979. That evening we were entertained with dinner and a string quartet from the Chicago Symphony at Fred Merkel's home located on Lakeshore Drive. It was a dazzling event for a young surgeon. Just the thought of being part of this community, who had made it their quest to find solutions to diseases where there had been neither hope nor life, were awe-inspiring. Ever since that time, the art and science of transplantation has fascinated me and I have dedicated my professional life to it.

Organ transplantation was developed as a surgical specialty with the surgeons having to address not only the daunting surgical difficulties, but also the issues of patient selection, immunosuppression, organ preservation, postoperative care and the multitude of essential details. The history of the surgeons' developing the field of transplantation cannot be changed; however, today, even if the surgeon remains the leader of the programs and transplant teams, transplantation is no longer the sole claim of surgery.

Indeed, today transplantation is a comprehensive department which is comprised of a tight knit fabric of specialists including surgeons, anesthesiologists, nephrologists, hepatologists, cardiologists, radiologists, infectious disease physicians, pathologists, coordinators, nurses, and administrators – to mention only some. Transplantation exemplifies the term multidisciplinary team. In fact, it did so long before the term was coined and popularized - by whom I do not know, but perhaps someone in a health care think tank somewhere; someone who did not know that this was already an established practice in transplantation. To those of us in the field of transplantation, however, this politically correct term is empty. If you, as a professional, are part of a transplant team, it really doesn't matter what your training and certificates say – you are on the liver, kidney, heart, or lung transplant team. That is your source of pride!

Here is Doug Tindall today with his wife and triplets. I transplanted Doug on December 1, 1987 at Baylor. He was a 19-year-old suffering from Crigler-Nijjar Syndrome. Since his transplant he has completed his college degree, gotten married, and fathered these three beautiful triplets. He is working as the Director of the Houston Disaster Relief and Emergency Medical Service. Doug Tindall serves as a shining example of the power of transplantation.

We have gone from being a specialty where only a handful of surgeons and a few nephrologists or gastroenterologists struggled with the failure of regular medicine and where survival was only hoped for but rarely seen, to being victims of our own accomplishments. Patients and their families now **expect** success. In the past we could only provide hope, now we deliver results. In fact, society at large is so used to hearing about our successes that it now expects us to provide the same safety, security and outcomes as is experienced in general healthcare. This has created a problem because society at large does not have even a rudimentary understanding or insight into the biological, surgical and logistical complexities involved in transplantation.

This leads us into the second part of today's talk – Regulatory Oversight. We should not expect that federal, state, or private organizations can understand the intricacies involved in transplantation. However, they have made it their business to organize and regulate how transplantation is performed. They use rules pertaining to general medicine and surgery, transfusion medicine, and to clinics open 9 to 5 and apply them to the field of transplantation.

It is hard for them to understand the social, psychological, and medical complexities involved in the workings of living donor organ identification. They lack insight into the logistical complexities involved in working up an organ donor who is hundreds of miles away at a small outlying hospital while at the same time arranging the actual transplant of an urgently admitted recipient.

These well meaning individuals formulate demands that, as an example, may in effect threaten the availability of living donors by making the transplant center requirements so unrealistic that they only succeed in slowing down and possibly deterring the transplant process. Additionally, this results in an unquestionably dramatic increase in the cost of providing healthcare with only a marginal improvement in patient safety.

We constantly hear about the escalating cost of healthcare, yet no one has ever bothered to calculate how much of the cost increase has been caused by regulatory demands. Safety is paramount and so is quality. However, safety and quality are not the result of signed forms but of established carefully designed processes. I am not convinced that transplantation, as practiced today, is significantly safer or better than 20 years ago, but then I have never claimed to be politically correct.

In the last few years, organ transplantation has turned into the most regulated field of medicine. It is the responsibility of the professionals in ASTS, AST, NATCO, and AOPO to engage ourselves in these ongoing developments. We must not simply say yes or compromise because the political climate currently favors the development of regulations, but we must fight unrealistic proposals from any institution populated by administrators and physicians not involved in transplantation. Not by categorically saying "No", though.

The transplant community must shoulder the responsibility to help develop regulations when justified and to make sure that whatever new regulations are developed that they are best for our patients and the future of our specialty.

In the past, the tendency has been for physician organizations to categorically deny problems and legitimate complaints from patients and the community. ASTS has recognized that such an approach leaves the professionals bypassed. Instead, ASTS sees it as a responsibility to our patients and the community to admit when something is wrong or when it does not work and assist in developing ways to improve the system and to prevent abuse. The solutions must be compatible with the clinical reality and support a sound functional system. During the past year ASTS has worked diligently with Senators Grassley and Levin, CMS, UNOS/OPTN, JCAHO, and FDA on a number of diverse issues. Our input has been uniformly very well received and listened to. My own opinion is that functionaries at these institutions were suspicious at first when meeting with us and expecting a traditional categorical "No" from us regardless of what was being presented.

However, after hearing that we call a spade a spade and that ASTS was there to deliver constructive criticism, we experienced extraordinary responses to our critiques. Sometimes it took a little more prodding, but in the end it is always for a greater good. This effort is the result of an organized, systematic review and critique of every regulatory document submitted to the public. Each and every document was reviewed and discussed by the entire ASTS Council with the participation of the appropriate standing committees such as Legislative, Living Donor, Standards, Curriculum, and Ethics to mention a few. Comments and drafts were worked on by a host of ASTS members. Thus, these comments are a true reflection of our membership, not just a small group of individuals and the result of these thoughtful comments have been uniformly well received. Assisting throughout these processes I want to mention the participation of Rebecca Burke, Diane Millman, and Peter Thomas from Powers, Pyles, Sutter, and Vervill who have been critical in this process, as well. It is important to note that ASTS does not accept as an answer that an agency does not make all the requested corrections. When this happens we convene again, make further improvements, and continue to work with whoever is making the recommendation.

At this point, I wish to express my sincere gratitude to Senator Grassley, Senator Levin and their staffs; to Dr. Thomas Hamilton and his staff at CMS; to Dr. Jim Burdick and his staff at HRSA-DOT; and to Dr. Timothy Pruitt and the staff at UNOS for their willingness to work constructively with us.. It should be noted that Dr. Budick's participation at the DOT is remarkably important. Having an experienced transplant surgeon at the helm that understands the issues and can explain them to administrators is of tremendous value. I fervently hope that we can continue this positive relationship into the future.

A secondary result of this rush to regulate the practice of transplant surgery and medicine is that progress and development are taking a back seat. The practice of transplantation is being frozen in its present state through regulations that makes yesterday's practice the only way to transplant. CMS, OPTN/UNOS and JCAHO will apply the rules, regulations, and standards of their respective organizations with scant consideration of new and perhaps better ways to perform transplants. These rules hinder centers from trying new and innovative solutions aimed at providing superior and more effective healthcare.

"Transplantation and modern immunology" were concepts created by "Ignorant Surgeons," in spite of the warnings from all theoretical scientists in the 1950s, 60s, and 70s."

Having been in the field of transplantation for more than 30 years, it is my strong opinion that had organ transplantation first been developed in the 21st century instead of in the 1950's, 60's, 70's and 80's – any and all attempts at organ transplantation would have been completely prevented or shut down by various review boards, who in their collective wisdom do not have the brilliance of individuals such as Francis Moore, Thomas Starzl, Roy Calne or Norman Shumway. At best, these surgeons would have been forced to implement rigorously defined randomized trials, even when the appropriate patient indications, the surgical technique, as well as the perioperative treatment protocols including immunosuppression, were for all intents and purposes unknown.. The results would have been disastrous and would have shut down all further attempts to transplant.

Galileo stated that the earth was not the center of the universe. As a result he was excommunicated for his theories by the Inquisition, the cardinals, and the Pope as being a heretic. Similarly, to this day we still do not completely understand the mechanisms that lead to operational graft acceptance. I believe our transplant forefathers would have been treated similarly if they had begun their quests today. They would have been excommunicated by the scientific and legal communities, as well as the popular press.

My conclusion is that the freezing of how to practice by regulations, together with the escalating costs due to regulatory mandates, are the biggest threat to the future of transplantation in the United States.

Fortunately, not everything is gloom and doom. We have accomplished a great deal this past year in our society. The hope and future of transplant surgery today, just as in yesteryear, depends on our new members. Our fellows of today will be the future leaders of transplant programs and of the American Society of Transplant Surgeons.

Most importantly, we are implementing a formal curriculum for transplant fellowships. The curriculum will consist of 28 modules addressing all facets of transplant surgery, including not only surgery and immunosuppression, but also pre-op evaluation and care, intensive care, post-op care and follow-up. The curriculum is expected to be fully implemented by next year. There will also be a formal certification in the foreseeable future. The Curriculum and the Fellowship Committees are to be commended for their work on this endeavor this past year. Parallel to the transplant fellows training program, ASTS has developed detailed recommendations for a curriculum for residents rotating through transplant services. This important work was undertaken after discussions with the American Board of Surgery and the Residency Review Committee. Every transplant program and transplant fellowship director in the United States and Canada received an outline for a resident curriculum last July. ASTS will closely follow the implementation of a residency curriculum along with the American Board of Surgery.

Medicine and especially surgery are still professions you can only truly learn through an apprenticeship. Formal study of science is fundamental to any practice of medicine. But to believe that a competent surgeon will spring forth after years in the library is an illusion. Surgery is a profession that can only be learned through an old fashioned apprenticeship. It is only through the careful development of the apprentice's diagnostic, surgical, and management skills under the watchful eye of a mentor that a professional will emerge. The entire history of surgery consists of an unbroken line of mentors and trainees. Surgeons say that we stand upon the shoulders of our mentors. In doing so each generation climbs a little higher. It is from this elevated perspective that we are able to see and understand what was once beyond the horizon for the previous generation.

There is more to training a surgeon than to simply teach professional skills. The training must also teach ethics and humanity, as well as learning to be humble. William Halstead was followed at Hopkins by Alfred Blalock, who trained Thomas Starzl in the principals of surgery. This only serves as an example to illustrate that transplant surgery has its roots in the fabric of general surgery. Thomas Starzl, the father of liver transplantation and modern immunosuppression, holds a monumental place in the history of transplantation.

Indeed, I would venture to say that even Marlon Brando, the Godfather, would be envious of Starzl's image. However, this may be the Brando image for which Tom was striving. One of Starzl's points of brilliance was his compassion for the patient. He refused to ever give up and amid a torrent of information, much with unknown significance, always kept his focus on the essentials. Finally, his mastery in surgery is the one reason we are here today. He and his peers of that generation persevered in spite of the obstacles. They succeeded and we are here to continue their legacy.

I arrived in Denver in 1979 to be trained as a second generation transplant surgeon by Thomas Starzl. I will never claim that I see further or understand the biology of transplantation nearly as well as Starzl. However, he gave me the opportunity to stand on his shoulders to catch a glimpse of the wonder on the horizon. What I saw has fascinated me ever since.

My fellows have stood on my shoulders for a short time and thus, become third generation transplant surgeons. My hopes and expectations for them are that they will climb higher to see what I will never see in my career as a transplant surgeon.

Even in an environment where it sometimes seems as if a perfect storm exists with new regulations, certifications, attempts to legislate the practice of medicine, and declining reimbursements, organ transplantation is an honest and noble profession. To be a transplant professional is fascinating, engaging and you know you make a difference. If I had a choice, I would do it all over again. However, if I had known what was in store for me, I do not know if I would have dared – Ignorance can be a wonderful thing.

The pride of my professional life is having been given the opportunity to play a small part in the development of solid organ transplantation, of patient care, surgery and immunosuppression; to be part of the creation of the Baylor Regional Transplant Institute in Dallas and Fort Worth; and for what is to me the ultimate honor, to be your president.

However, all this pales in comparison to those next to me, my family - Tina, my wife, my love, my friend, my confidant; my sons Marcus, Erik and Philip without whom life would lack purpose. I thank you for listening to me and for choosing to be part of the noble profession of organ transplantation.

The tragedy that struck the University of Michigan and the transplant community on June 4, 2007 was a harsh reminder of the sacrifices that are made by people engaged in transplantation. As health care professionals we have grown up learning to make every effort that is humanly possible for our patients; working night and day – as if it is not a really big deal – with little or no sleep, never giving up even when the odds seemed insurmountable. However, retrieving deceased donor organs means taking a step that requires a different level of engagement. There are different levels of risk one may be exposed to when making a donor trip. I remember flying in a Lear Jet at 1000 feet from Chicago to Pittsburgh because the door had frozen and could not be closed. Our concern was not with the fuselage door but with the mounting ischemia time for the liver in its cooler; or the time in upstate New York being driven in a country taxi on roads so slick that you could push the car sideways; or the excited sheriff who drove us at 100 mph through the main street in a little town in Missouri. But for the Michigan team it did not take a fool pushing the limits, only a mechanical failure of an otherwise flawlessly

planned and executed organ retrieval run. Pilots, donor coordinators, residents and surgeons were lost. We all lost something. Our society is working with the University of Michigan to better understand the practices that exist for donor retrievals in the U.S. with the hope of learning something that can lessen the peril for all those involved.

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