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ASTS
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LETTER FROM THE p r e s i d e n t



Dear Friends,

I have recently been asked whether the ASTS is an exclusive society. Admittedly, living in a country in which freedom and equal opportunities are of highly valued, exclusiveness may be an anti-thesis to how we should present ourselves to the outside world. Yet, we do hold high (and maybe exclusive) standards for our members, which is a mere reflection of the efforts of the ASTS to provide the best possible care from professionals who know well the field of Transplantation Surgery.

Our society values high standards and wishes to advance an agenda that will lead to better transplant outcomes, provide outstanding opportunities for continuing surgical education, and participate in research endeavors that translate to better care of our patients. These issues were addressed in our yearly strategic meeting, in which we discussed the means by which the ASTS can work with various government agencies and UNOS in order to present an accurate assessment of what should be considered the standard criteria for accreditation of transplant programs and transplant surgeons. The ASTS Council believes that input from our membership is essential in order to avoid the implementation of unrealistic and inappropriate regulations, all of which may restrict our ability to provide the best care for our patients. Members of the Council and the Chair of the

Standards for Organ Transplantation Committee will initiate a discussion with the membership, with the attempts to further define what is considered fair and acceptable standards for surgeons and transplant programs and yet maintain a high level of quality and safety for our patients. The recommendations from ASTS members will become available to any regulatory body which wishes to consult our Society and/or coordinate the implementation of such standards in the transplant community.

The potential for the ASTS to have an impact on these issues is clearly dependent on the ability to have access to members of Congress and other government departments, such as CMS, HRSA, and various House and Senate committees, all of which are involved in and responsible for implementation of these regulations. To approach these bodies, the ASTS has established efforts in Washington resulting in continuous transfer of necessary data and information to members of Congress, testifying in various committees, and submission of our opinions and recommendations. These are efforts that have been successful, work well for the transplant community, and have had a positive impact on our profession. Standards for programs and transplant surgeons is one of the more recent topics that is constantly under re-examination. Examples of other important issues are as diverse as Donor incentives, Medicare payment for immunosuppressive medications, and appropriate reimbursement for transplant procedures.

It is obvious that the ASTS must set up short and long term priorities for our political agenda, and we welcome your involvement and suggestions. Your concerns about these issues must be heard and I encourage you to keep an open and direct line of communication with me, or any other Council representative. Your input will be important, specifically in any future survey that you may receive regarding topics such as program requirements and surgical standards. It is our responsibility to clearly represent ALL our membership concerns, and we are committed to adhering to this important principle.

Just as reminder, please make all efforts to attend the upcoming 4th Annual ASTS Winter Symposium. This forum is becoming an important platform for presentations focusing on surgical topics, and is geared toward the need of the young and less established members of our Society, with expert input from the seasoned "elders". The upcoming conference "Surgical Challenges in Transplantation" will be in Scottsdale, Arizona, on January 23-25, 2004.

Best Regards,

Abraham Shaked, MD, PhD
President

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The ASTS Council met on September 23-24, 2003 in New York, New York. The following are committee reports presented at this meeting:

Awards Committee Report:

Thomas Peters reported that the short-term goals of the committee are looking at better communication with awardees and information about the career outcomes of the awardees. ASTS will post the list of past awardees on the website of the Society.

Education Committee Report:

Mitchell Henry requested and the Council approved the following recommendations of the Education Committee of the following accreditation applications: The University of Alberta at Edmonton for training of one fellow every two years in liver transplantation; Tufts New England Medical Center for training one fellow every two years in kidney and liver transplantation and for renewal application to approve Stanford University's reaccreditation for kidney and liver programs.

Membership Committee:

David Mulligan reported that ASTS currently has 939 Members and eight pending applications.

Scientific Studies Committee Report:

Giacomo Basadona reported via written report that the committee has met several times on the phone during last year and in person during the most recent ATC meeting. One of its major initiatives is the research web page, a concept developed by some of the most junior members of the committee. Its goal is to foster collaborations among the Members of the Society in the field of clinical and basic research. Members are encouraged to post their research projects on the "research web page" when looking for possible collaborators and/or ideas on how to get the project started and eventually funded. To access the site go to www.ast.org and click into the Members Only section.

Thoracic Organ Transplantation Committee Report:

Mark Barr and Joren Madsen report that the Committee will be working with the STS once again this year on the 4th Annual joint ASTS/STS Symposium at the Society of Thoracic Surgeons meeting in San Antonio in January 2004. Topics and speakers will be: Current Strategies for the Optimal Utilization of Cardiac Assist Devices (Robert Kormos); Technical Considerations in Lung Transplantation (G. Alexander Patterson); and Immunosuppression in the 21st Century (James S. Allen). The session is anticipated to have 200 attendees, at least 50% of who should be surgical trainees. The Committee is also working to create a set of descriptions for "backbench" surgery in heart and lung transplantation, parallel to the efforts that have been made in abdominal transplantation by Mike Abecassis and the ASTS Reimbursement Ad Hoc Committee.

Vanguard Committee Report:

Sandy Feng reported about the 4th Annual ASTS State-of-the-Art Winter Symposium and the program prepared by the planning committee. She noted that there would be a two day pre-meeting course on fundamentals of clinical research transplantation. She next reported that the database project was moving along and that the first phase, which was designing and implementation of electronic membership application to enable easy transfer of demographic and research activities has been completed. They are currently working to create a mechanism to enable preexisting Members to update their profiles and the final phase will be an ASTS Pubmed search capability. 🦋



ASTS Foundation Report:

The Board of the ASTS Foundation met on September 24, 2003 in New York City. The Board voted upon and approved the mission statement of the Foundation which is: The American Society of Transplant Surgeons Foundation will advance the field of Transplantation by supporting the mission and activities of the American Society of Transplant Surgeons. The mission of the ASTS Foundation is to serve as the endowment vehicle of the ASTS. Funds generated will be used to provide support for ASTS sponsored initiatives such as education, fellowships and other training, and research.

Major legislation affecting transplantation continues to move forward as the first session of the 108th Congress approaches. Major structural reform of the Medicare program, including a new prescription drug benefit and a physician fee schedule update as well as organ donation legislation and appropriations for key federal transplant programs are all on the table this fall. Meanwhile, structural reform of the Medicaid program appears to be sidelined until next year along with medical malpractice reform legislation, which appeared to be dead in the water until President Bush renewed his call for a reform bill.

If Congress fails to act on Medicare reform this year—its current prospects being no more than 50/50—it is unlikely that the myriad reforms contained in the bill, including reform of the physician fee schedule, will be enacted into law. Furthermore, ASTS is actively involved with securing passage of organ donation legislation this year but time for passage of such a bill is getting short.

Medicare Reform and Prescription Drug Update

As reported in the summer issue of *Chimera*, Congress was swiftly moving toward passage of a comprehensive Medicare reform and prescription drug bill in June. In the last week of June, both the House and Senate passed competing Medicare bills that would reform Medicare in perhaps the most significant reform of the program since its inception in 1965. Both bills rely heavily upon private, managed care models for the provision of

new Medicare plans and a prescription drug benefit. The House bill contains a controversial provision to begin Federal Employee Health Benefit Plan-style competition in 2010. Both bills would also reform many reimbursement formulas in traditional fee-for-service Medicare including reform of the physician fee schedule.

Following passage of the bills in June, both houses appointed Conference Committee members and set to work reconciling the vastly different approaches to Medicare reform and prescription drug coverage taken

by the House and Senate. Despite the good intentions of conferees, little progress was made in late July or during the August Congressional recess with both parties posturing for advantage during the fall, when major action is expected. As of mid-September, the conferees have reached tentative agreements on several non-controversial elements of the Medicare bills: Medicare regulatory reform (which ASTS has long supported), a prescription drug discount card to provide some financial assistance until implementation of the drug benefit in 2006,

ASTS will be actively involved in the Medicare debate and will continue to press for physician fee schedule reform and coverage of immunosuppressive drugs.

and a limited number of provider payment adjustments, including several provisions of interest to ASTS (see below).

Despite internal political difficulties among Republican conference leaders over how to resolve rural provider payment issues and the scope of managed care involvement in the Medicare program, President Bush and Senate Majority Leader Bill Frist (R-TN) have both expressed their confidence in Congress passing a Medicare bill before the end of the year. Frist stated that problems should be expected in the process to reach an agreement because of the complexity of the legislation. Optimism among House Republicans appears to be limited, though, as most House Republicans are insistent on strong private sector involvement with new Medicare plans.

GOP Medicare conferees have yet to decide whether negotiators or President Bush should set a firm deadline to finish work on a final Medicare bill but if one were selected, it would be no later than November 11, 2003. Finance Chairman Grassley has been encouraging conferees to adopt a deadline of Columbus Day, October 13. Frist stated that he “would like to see [a final bill] by the end of September.” However, many health care observers caution this deadline as

highly unrealistic with actual negotiations likely extending late into the fall if a compromise appears possible.

Although the full conference committee has formally adopted staff-led compromises on the regulatory reform, drug discount card, and provider provisions, these provisions are what many describe as “low hanging fruit.” Among the issues still far from compromise are as follows:

Prescription Drug Benefit—Both the House and Senate bills call for drug benefits to be delivered either through private “drug-only” insurance plans, or as part of more comprehensive coverage by a “preferred provider organization,” HMO, or other private plan. The Senate bill calls for an annual deductible of \$275, after which the plan would pay half (50 percent coinsurance) of the next \$4,225 worth of drugs. After that, beneficiaries would have to pay all their own bills unless they reach \$3,700 in out-of-pocket spending, after which the plan would pay 90 percent of remaining drug costs for the year.

The House bill calls for an annual deductible of \$250, after which the plan would pay 80 percent of the next \$1,750 worth of drugs. After beneficiaries spend \$3,500 out-of-pocket, the plan would pick up 100 percent of drug costs for the rest of the year.

Both plans include special help for beneficiaries with low incomes and the out-of-pocket threshold for “catastrophic” coverage in the House bill varies for those with more than \$60,000 in annual income.

Premium Support—The House bill, but not the Senate bill, calls for competition, beginning in the year 2010, between private health plans and Medicare’s traditional fee-for-service plan in areas where at least two private plans are offered.

This is perhaps the most significant difference between the bills that could slow the conference. Republicans maintain the provision will hold down Medicare costs, while Democrats believe it would effectively “privatize” the Medicare program and cause Part B premiums to be higher for beneficiaries who remain in traditional Medicare, who would more likely be those with complex, chronic, or expensive conditions. If conferees are able to reach a compromise on this issue early in the process, it would create a great deal of momentum to work out other controversial provisions.

Federal Fallback—The Senate bill, but not the House bill, calls for the federal government to provide a Medicare drug benefit in regions where fewer than two private “drug-only” plans are

ASTS will also continue to be engaged in the debate over organ donation legislation and will continue to work with key staff and Senators on passage of legislation this year.

offered. House Republicans are vehemently opposed to such a “fallback” because it would effectively create a federal drug plan that would have to set prices for covered pharmaceuticals. However, the lack of a fallback could prove to be a “poison pill” for Senate Democrats who supported the original bill.

Health Savings Accounts—The House bill incorporates the “Health Savings and Affordability Act,” which would authorize creation of two types of tax-preferred savings accounts. “Health Savings Accounts,” similar to Medical Savings Accounts, would be available to those covered by health plans with deductibles of at least \$1,000 for individuals and \$2,000 for families. “Health Savings Security Accounts” would be available to those with plans with lower deductibles; \$500 for individuals and \$1,000 for families. Money in both accounts would accrue tax free, and could be used for “qualified medical expenses” including medical treatment, prescription drugs, and long-term care services or insurance premiums. Democrats will oppose the inclusion of these non-Medicare provisions in the Medicare bill because these accounts, in their view, tend to appeal to healthier and younger people, thereby raising insurance costs on sicker and older populations. The

biggest stumbling block for Republicans is the \$174 billion price tag attached by the Congressional Budget Office.

Immunosuppressive Drug Coverage

Neither the Senate and House Medicare bills include a provision relating to coverage of immunosuppressive drugs in Part B of Medicare. Under both bills, immunosuppressive coverage would continue under Part B unchanged. Beneficiaries not qualifying for immunosuppressive coverage under Part B could receive coverage through the proposed privately-administered drug benefit, enhanced fee-for-service option, through a Medicare Advantage plan, or, beginning in 2010 under the House bill, a Medicare FEHBP-style plan. Under all of the proposed drug coverage options, issues relating to therapeutic classification, formularies, and tiered copayments could complicate the ability for patients seeking a specific immunosuppressive drug therapy to receive the appropriate course of treatment.

Although this initiative was spearheaded by the National Kidney Foundation, ASTS has been actively involved in speaking with members of the House and Senate regarding inclusion of this immunosuppressive drug

provision in the Medicare bill. However, the chances for inclusion are very slim at this point. The general feeling among members of both committees is that coverage should be obtained under the proposed drug benefit, not by increasing coverage under Medicare Part B.

Payment Methodology Demonstration for Surgical First Assisting Services of Certified Registered Nurse First Assistants Included in Medicare Bill Compromise

A demonstration project regarding the Medicare coverage of Surgical First Assisting Services of Certified Registered Nurse First Assistants (CRNFA) was included in the Senate-passed Medicare bill and was adopted officially by conferees on September 9. It should be noted, though, that this provision, along with the provision on pancreatic islet transplantation described below, is part of the larger Medicare bill and will not become law unless the full reform bill is enacted.

Under the demonstration, Health and Human Services (HHS) would establish a new payment methodology for surgical first assisting services furnished by a CRNFA to Medicare beneficiaries. Under the language, a CRNFA is defined as a registered nurse

who is 1) licensed to practice nursing in the State in which the surgical first assisting services are performed; 2) has completed a minimum of 2,000 hours of first assisting a physician with surgery and related preoperative, intra-operative, and postoperative care; and 3) is certified as a registered nurse first assistant by an accreditation body recognized by the Secretary of HHS. The demonstration would occur over a three-year period in five states. The locations would be determined by the Secretary.

The new payment methodology under the demonstration project would be the lesser of either 1) 80 percent of the lesser of the actual charge for the services; or 2) 85 percent of the amount determined under the physician fee schedule as if furnished by a physician.

Medicare Pancreatic Islet Transplantation Demonstration Included in Medicare Bill

Also adopted by the conferees on September 9 was a provision establishing a Medicare Pancreatic Islet Cell Transplant Demonstration Project. The Secretary of HHS would establish a demonstration project to test the appropriateness of pancreatic islet cell transplantation in the case of Medicare beneficiaries with Type I diabetes and end stage renal disease. The testing would be conducted over five years. Under the demonstration, the Secretary will submit a report including legislative and administrative recommendations to Congress no later than 120 days after termination of the project. The Secretary will also create a payment methodology that, if possible, bundles payments for all items and services used throughout the project.

Physician Fee Schedule Update

The Centers for Medicare & Medicaid Services (CMS) published a proposed

rule on August 15, 2003, that will update payment rates under the Medicare physician fee schedule for 2004, as well as revise a number of other policies affecting Medicare Part B payments under the fee schedule. The rule proposes to cut physician payments by 4.2 percent in 2004, but that number could change as provisions contained in the Medicare reform legislation seek to reduce or eliminate the cut.

The House bill would increase Medicare provider payments at least 1.5 percent per year in 2004 and 2005 (over 2003 levels) and permanently correct the sustainable growth rate (SGR) formula, which is viewed by many as a flawed method of updating physician payments. The Senate bill, despite expressing the “sense of the Senate” that the payment formula is flawed and that physician payments should be increased, does not change the current law directly. Rather, the Senate contains “placeholder” language to allow a conference on the issue with House leaders.

The current physician fee schedule is updated on an annual basis according to the SGR formula specified by statute, which is designed to rein-in the growth in outlays for physician services. The government lowers Medicare payments when the amount spent on provider services exceeds the SGR. The SGR in turn is calculated based on medical inflation, the projected growth in the domestic economy, the projected growth in the number of beneficiaries in fee-for-service Medicare, and changes in law or regulation. Largely due to slow growth in the economy and to a significant growth in physician outlays in 2002, CMS advised the Medicare Payment Advisory Commission (MedPAC) in March that the “update” for 2004 would be (- 4.2) percent. If Congress does not finish work on Medicare reform before January 1, 2004, and include provisions similar to the House

bill, the 4.2 percent cut will take effect on the first day of the new year. ASTS is working with many other physician organizations to ensure this does not occur.

Action Expected this Year on Organ Donation Legislation

Major organ donation legislation, for which ASTS and other transplant groups have been advocating, has passed the House, been introduced in the Senate, and is expected to see action later this year. A version of the legislation passed the House of Representatives on March 12, 2003, by a vote of 425-3. The Senate bill, S. 573, which was introduced by Senate Majority Leader Bill Frist (R-TN) on March 6, 2003, is beginning to gain support in the Senate for action this year. ASTS has sent letters of support to both House and Senate sponsors and has met with staff from Senator Frist’s office and the Chairman of the Health, Education, Labor, and Pensions Committee, Judd Gregg (R-NH), to share our support and concerns on the pending legislation.

In discussions with key Senate staff, ASTS has received a commitment for consideration of major organ donation legislation this year. Generally, the Frist bill, S. 573, represents the “consensus” of many members with interests in organ donation. ASTS is actively involved with staff members from the House and Senate on achieving a comprehensive organ donation bill.

Medicaid “Dual Eligible” State Relief in Medicare Bill; Structural Medicaid Reform Debate Expected Next Year

In the 108th Congress, major efforts to reform the Medicaid program are underway. The inclusion of \$20 billion over two years in state fiscal relief in the tax legislation enacted in early June

has helped states somewhat and has taken some pressure off the Congress to pass more structural reforms. In addition to the initial state fiscal relief, provisions contained in the Medicare reform legislation and upcoming structural reform plans next year have the possibility to radically change how the Medicaid program is financed.

The House Energy and Commerce Committee, which has already held a hearing on Medicaid reform, has become increasingly vocal about the need for comprehensive reform of the program. The Bush Administration also has been vocal about Medicaid reform and unveiled in February an outline for reform in its FY 2004 budget. The National Governors Association (NGA), which has been a strong advocate and national leader for reforming the Medicaid program, failed to achieve a highly touted bipartisan Medicaid reform plan earlier this year. The NGA has expressed interest in revisiting the issue next year at the conclusion of the Medicare reform effort.

Medicaid provisions in the Medicare reform bill could complicate the expected Medicaid reform debate next year. Both House and Senate Medicare bills would reform the way the federal government reimburses states for costs associated with approximately 6.2 million “dually eligible” beneficiaries (enrolled in both Medicare and Medicaid). The NGA and other health care advocacy groups are supportive of the federal government assuming the high costs of these beneficiaries since under current law Medicaid pays for their prescription drug benefits.

The Senate Medicaid provision would provide approximately \$17.5 billion over 10 years to states to help defray the costs associated with providing drug benefits to dual eligible

beneficiaries. Under this provision, the federal government, not the states, would pay for Medicare Part B premiums for certain low-income seniors or persons with disabilities and would establish 100 percent matching for Medicare Part A deductibles and coinsurance for other certain low-income beneficiaries. However, because states often have differing eligibility levels for the categories covered in the legislation, the amount of fiscal assistance to each state is predicated on many state-specific details.

The House provision covers Medicaid costs that states pay for prescription drugs, but does not relieve states of non-drug Medicaid expenditures like the Senate bill. However, this approach is predicated on a steadily increasing federal match increasing up to 100% for all drug costs by 2020. The increasing match, which phases in slowly over 16 years, reduces the CBO score and immediate relief to states. The National Governors Association has endorsed the House provision as have many other major advocacy organizations. The Bush Administration has endorsed the Senate approach due to its lower cost.

ASTS Submits Testimony to Appropriations Subcommittee on FY 2004 Priorities; House and Senate Move Forward with Appropriations Process

ASTS submitted written testimony to the House and Senate Appropriations Subcommittees on Labor, HHS, and Education on fiscal year 2004 federal spending levels during the spring of 2003. ASTS focused on funding increases for the Division of Transplantation within the Health Resources and Services Administration and increased funding

for NIH research, including research on transplant surgery. Final funding levels for the previous fiscal year, FY 2003, were in concert with ASTS’ FY 2003 recommendations, namely, \$25 million (which, upon final passage was \$24.8 due to an across-the-board spending cut of .66 percent) for the DOT and a 13% increase for NIH. ASTS’s recommendations for FY 2004 are \$30 million for DOT and a 10% increase for NIH.

The House of Representatives passed the Labor, HHS, and Education spending bill in early July and the full Senate approved its bill in early September. Both bills have funded DOT at \$24.8 million. This represents level funding from FY 2003, but still represents an overall non-cumulative increase of \$10 million annually since FY 2001. A major amendment introduced by Senator Tom Harkin (D-IA) to increase appropriations for the NIH failed on procedural grounds. The amendment received 52 votes, but was forced to overcome rules that mandate a 60-vote majority for amendments that would exceed current budget authority. The amendment would have brought NIH funding closer to ASTS-recommended levels.

The bill now moves to what will likely be a contentious conference committee. None of the 13 appropriations bills have been resolved for FY 2004 even though the new fiscal year begins October 1, 2003. It is very doubtful that the Labor, HHS, Education bill will be completed before this deadline, but it is expected to be resolved later this year.

Advisory Committee on Transplantation

The HHS Advisory Committee on Transplantation (ACOT) is sched-

uled to meet in Washington on November 6-7, 2003.

In conjunction with the next ACOT meeting, members of the “Transplant Roundtable,” a Washington, DC, based coalition of transplant-related advocacy organizations of which ASTS is a member, plan to consider releasing individual statements reaffirming donor rights. The concept of this approach is to affirm that the wishes of the decedent donor may not be overruled by family members after death and, thereby, bring this donor rights approach to greater national attention. At its May 2003 meeting, the ASTS Council adopted and reaffirmed ASTS’s commitment to this policy. ASTS is actively involved with the Roundtable and will continue efforts to work with ACOT and HHS on donor rights and other organ donation policy.

Medical Malpractice Reform Legislation

On July 9, Senate Democrats blocked a Republican-backed medical malpractice bill, S.11, that would have capped noneconomic damages in malpractice lawsuits at \$250,000. The 49-48 vote, largely along party lines, fell 11 votes short of the 60 required to break a Democratic filibuster and bring the measure up for a formal vote. All 49 votes for the measure were cast by Republicans, while two Republicans joined 45 Democrats and one independent in voting against the measure. The House earlier this year passed a bill, H.R. 5, similar to the Senate legislation. The House bill, sponsored by Congressman Jim Greenwood (R-PA), would cap noneconomic damages in malpractice lawsuits at \$250,000 and would allow punitive damages of \$250,000 or twice the amount of economic dam-

ages, whichever is higher. The legislation covers lawsuits filed against physicians, HMOs, pharmaceutical companies and medical device companies. The bill also would allow state governments to increase or decrease the cap; the legislation would not cap economic damages, which include medical costs and lost wages.

Given this defeat, it was unlikely that the Senate would return to this issue in the near future. But President Bush recently reaffirmed his interest in passing a bill, so the prospects for passage are at least marginally improved.

HRSA Division of Transplantation Awards Organ and Tissue Donation Grants

On August 20, HHS Secretary Tommy Thompson announced 13 grants worth \$4.27 million to support social, behavioral and clinical intervention programs that lead to increased organ and tissue donation. Grants will be awarded from two HHS grant programs: Social and Behavioral Interventions to Increase Organ and Tissue Donation, and Clinical Interventions to Increase Organ Procurement.

The social and behavioral interventions program, established in 1999, emphasizes rigorous methodology and evaluation to test the efficacy of interventions meant to increase organ and tissue donation. Total funding for the eight awards is \$2,776,690.

The clinical interventions program, funded for the first time in FY 2002 as part of Secretary Thompson’s “Gift of Life” Donation Initiative, evaluates clinical interventions to increase the number of organ donors and the number of organs recoverable from existing organ donors. It also promotes research to evaluate and dis-

seminate model interventions with the greatest impact on donation. This year’s grants will support five projects, totaling \$1,493,728.

Conclusion

It is likely that major action on Medicare will extend into the fall and possibly into the winter. If legislation passes, it will represent the most significant reform of the Medicare program since its inception in 1965 and will significantly shift Medicare toward private insurance as a model for the provision of Medicare-mandated benefits. ASTS will be actively involved in the Medicare debate and will continue to press for physician fee schedule reform and coverage of immunosuppressive drugs. ASTS will also continue to be engaged in the debate over organ donation legislation and will continue to work with key staff and Senators on passage of legislation this year. 🐾

Prepared by Peter W. Thomas, Esq., ASTS Legislative Counsel; and Dustin W.C. May, Legislative Director, Powers, Pyles, Sutter, and Verville, PC.

Regulatory and Reimbursement Update

Over the past several months, ASTS has been involved in a number of initiatives related to Medicare coverage of and payment for transplant services. ASTS has been active with respect to Medicare payment both for transplant surgeons' professional fees and hospital payment that may impact transplant patients' access to medically necessary hospital services.

Medicare Coverage:

CMS is expected to issue a final coverage determination on ventricular assist devices very soon. In March of this year, ASTS, represented by Robert Kormos, MD, presented testimony before the CMS Medicare Coverage Advisory Committee supporting the extension of Medicare coverage for ventricular assist devices (VADs) as destination therapy for patients with end-stage heart failure who are not eligible for a transplant. The Advisory Committee voted in favor of extending coverage for VADs as destination therapy for patients who meet the criteria of the REMATCH study. The Committee also recommended that patients first be evaluated by a heart transplant center. The Committee was also in agreement that hospitals performing the procedure should meet certain facility requirements; however, the Committee did not make specific recommendations on what those requirements should be.

CMS was to have issued a national coverage decision by September 15 of this year. However, as of the time this issue went to press, no decision had yet been released.

Medicare Payment:

Physician Payment: Living Donor Liver Hepatectomy Codes Expected to be Included in Medicare 2004 Fee Schedule

In the last issue of Chimera we reported that the AMA's Relative Value Update Committee (RUC) had made recommendations to CMS regarding work relative value units for the new living donor liver hepatectomy codes. Relative value units are multiplied by the Medicare dollar conversion factor to determine the amount Medicare will pay for a service. The RUC accepted ASTS' recommendations, and has recommended work relative value units (W-RVUs) for the living donor hepatectomy code that are significantly higher than the W-RVUs that are assigned to the single living donor hepatectomy code that is currently available.

The RUC did not finalize recommendations to CMS on certain aspects of the practice expense component of the service and indicated in its report that it would defer to ASTS and CMS on this issue. The practice expense relative value units are based primarily on office overhead and labor of the physician's employees - both clinical and administrative. At issue was the amount of pre-service clinical staff time that is spent with the living donor. ASTS and CMS held a conference call in late July and reached a consensus on the appropriate amount of pre-service time for purposes of the practice expense inputs. We expect that the 2004 Medicare Fee schedule, to be published this fall, will include the new living donor hepatectomy codes and the RVUs will reflect the RUC and ASTS recommendations.

Physician Payment: ASTS Urges CMS to Restore Payment Reductions for Several Transplant Codes

ASTS will send a letter to CMS later this month urging that proposed payment reductions for transplant procedures in the 2004 Medicare physician fee schedule be restored. The reductions are believed to be due to standardization of certain practice expense inputs related to clinical staff time that were applied to all surgical procedures. However, the standardization appears to have had a disproportionately negative impact on transplant procedures.

Hospital Payment: ASTS to Seek Increases in Medicare Payment for Certain Immunosuppressive Drugs

ASTS will submit comments to CMS later this month on hospital outpatient reimbursement for certain immunosuppressive drugs. Last year ASTS was successful in restoring some of the proposed payment cuts for a number of anti-rejection drugs. This year, the proposed cuts are not as widespread - only two drugs are affected (OKT3 and Thymoglobulin) - but the proposed payment appears to be below hospital acquisition costs. ASTS will present CMS with data on hospital acquisition costs for these two drugs and urge that payment be increased to at least cover hospital costs.

ASTS is Seeking New CPT Codes to Describe Backbench Work on Donor Organs

ASTS is preparing applications for several new CPT Codes to describe backbench or back table dissection of donor organs prior to transplant. ASTS' request to the AMA's CPT Editorial Committee, to be submitted in October, will include new codes to describe standard backbench work and additional reconstruction work on donor organs. ASTS hopes to have the new codes approved in time for inclusion in the 2005 edition of the CPT.

Other Issues:

*** Generic Substitution of Immunosuppressive Drugs**

ASTS has prepared a letter to Secretary Thompson on the issue of inappropriate substitution of generic versions of immunosuppressive drugs without the physician's knowledge and will urge the adoption of policies to prevent this practice.

*** New Transplant Center Regulations to be Published this Winter**

CMS is in the process of developing new regulations for transplant centers which will likely contain new volume standards for transplant procedures and new survival rates that Medicare certified transplant centers will be required to meet. ASTS has been in telephone con-

tact with CMS staff in charge of the regulations and we expect that ASTS representatives will meet with CMS staff once the proposed rule is published. CMS expects the publication date of the proposed rule to be sometime in January of 2004. ❧

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Compliance

Emerging Compliance Issues in Organ Transplant Reimbursement: Seven Questions Every Transplant Center Should Ask

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Organ transplants, one of the most extraordinary life-saving advancements in medical history, are also among the most expensive and complex services for hospitals to provide from operational, reimbursement and regulatory perspectives. Given the high cost of organ transplants, both the surgery itself as well as the pre- and post-transplant care necessary for successful outcomes, payors, including Medicare, pay special attention to payment and compliance issues surrounding organ transplants.

As a result of the complicated mechanics of transplant reimbursement, hospitals and health systems are at a significant risk for mistakes, false claims, and other compliance-related deficiencies. Indeed, BNA's Health Care Fraud Report documented a case involving Sharp HealthCare in California that led to a \$6.2 million settlement based on allegations of improper handling of various elements of transplant reimbursement (7 HFRA 387, 5/14/03). Another recent investigation of Tampa General Hospital in Florida turned up findings of cost report compliance issues that identified \$1.4 million in overstated costs (7 HFRA 366, 5/14/03).

Moreover, it appears that the Office of Inspector General (IG) of the Department of Health and Human Services (HHS) is currently surveying transplant programs nationwide to gain more information on the subject and is expected to look carefully for possible reimbursement violations. In fact, the IG's Work Plan for FY 2003 lists two areas of scrutiny related to transplant programs, whereas the FY 2002 Work Plan did not have any areas of focus devoted exclusively to Transplant Programs.

Complications in managing a transplant program are not due just to Medicare regulations, but issues arise because each organ (liver, kidney, heart, etc.) and each payor has their own separate set of complexities that must be managed. For example, payment for services provided to living organ donors is an issue in liver and kidney transplants, but not in heart transplants. Organ procurement reimbursement can be fairly straightforward until cadaveric organs are procured at one facility but used in several different facilities. Different payment mechanisms negotiated by a hospital's contracting department cause complex coordination of care and financial arrangements based on payment mechanisms varying from case-rate to per-diem to fee-for-service to global or split billing.

As with much of billing in the industry today, compliance is dependent on day-to-day careful execution of complex and detailed accounting and careful monitoring.

Regardless of how many payor contracts a program has, Medicare's requirements and regulations tend to set the tone for how a program establishes its clinical operations and the resulting reimbursement and compliance efforts. For example, the technical component of pre-transplant services are reimbursed by Medicare on a cost-plus-margin basis through a hospital's cost report, while the technical components of the surgery itself and the post-transplant services are reimbursed according to a fixed fee schedule. Of course, professional services are reimbursed separately by Medicare based on the physician fee schedule.

According to a recent report from BCS Research, tissue and organ transplantation in the United States cost \$17.3 billion last year and is expected to grow at a 3.5 percent annual rate, which will amount to an estimated \$20.5 billion by 2007.

More generally, the report documented that half of the health care expenditures in the United States each year are to treat the consequences of organ failure or tissue loss, an amount that exceeds \$600 billion.

With this much money on the table, it is not surprising that transplant reimbursement is extremely complex. And with such scrutiny being placed on hospital reimbursement, now is a critical time to raise the issue of transplant cost reporting and operations to identify possible risk areas at your institution.

Key Components of Transplant Reimbursement Compliance

Regardless of the patient's payor or the organ being transplanted, a key component to ensuring compliance is appropriately and meticulously accounting for expenses. One of the most significant nuances of organ transplant is the division of the care into phases: transplant evaluation, pre-transplant, transplant surgery and post-transplant. The common thread amongst most payors is that they have different payment mechanisms for each phase. Most commonly, however, the main division is between pre- and post-transplant.

Careful tracking mechanisms for distinguishing between the services provided for pre-transplant ("organ acquisition") and post-transplant related care must be diligently maintained and all of the expenses and costs incurred for patient care must be tracked in this

manner. In particular, staffing expenses (both clinical and administrative), building and occupancy costs, supply expenses, overhead allocations, and physician expenses that are devoted to pre-transplant services are reimbursed via the cost-report, whereas post-transplant services are paid via DRG or APC prospective payment mechanism based on the claims filed for the services provided.

Health care executives and their management teams should ask a number of key questions in order to protect themselves against risks of potential reimbursement problems. Based on experience, asking the following questions and identifying the following issues will allow you to determine whether or not your program is unnecessarily exposed and help set a course for remedying any identified areas of exposure:

1. Do We Have Staff Providing Both Pre- and Post-Transplant Services?

For various reasons, transplant programs often use the same staff to provide a patient's care from the evaluation through their time on the wait list, during the transplant itself, and throughout their often lengthy follow-up care process. From a provider / patient relationship perspective, this method of staffing makes sense. However, given the payment mechanisms involved, experience indicates it is "cleaner" for the operations to mirror the reimbursement and for the staff to be segregated by function. The expenses are then much more easily reported as such.

Which of our staff members should be tracking their time?

If the pre- and post-transplant functions of a program are indeed being performed by the same employees, then any employee who is performing duties for both should be tracking their time for each service. This includes transplant nurse coordinators, financial coordinators, social workers, medical directors, secretaries, receptionists, billing coordinators, home health nurses, dieticians, as well as managers and supervisors.

How should our staff be tracking their time?

Unfortunately, time tracking is a time-consuming, tedious and generally manual task. The cleanest method of segregating a large portion of the time spent by the staff (collectively) on pre- and post-transplant patients is to designate pre-transplant clinic days and post-transplant clinic days (or mornings versus afternoons) and then allocating the total expenses for those clinics based on the relative number of clinic sessions. This split will help ease the administrative task of time tracking for the clinical employees, but to a lesser extent for the support staff as well. For functions that cannot be so clearly separated, worksheets, time studies, motion reports or other documentation methods (e.g. number of phone calls, number of registrations, etc.) should be used to track time spent on combined activities. Staff should track time ideally one week per month and time should be aggregated on a quarterly basis.

Tracking "by default" may also be an option for staff who spend the great majority of their time on either pre- or post-transplant activities, but may spend a few hours a month on non-related duties, such as separately reimbursable research activities. These staff can document only the time spent on the research or other minority project, and the rest of their time can be reasonably assumed to have been spent on the main duties.

Will this process guarantee that our staff expense reporting is accurate?

To ensure that this tracking effort is not wasted, a couple of important activities must be performed.

First, the tracking documents should be periodically monitored internally or externally audited to ensure that they reflect reality as much as possible and to correct problems identified before they appear on the cost report. Employee time sheets should be reflective of the actual hours worked. For example, while this seems obvious, experience indicates that unless monitored an employee who worked a 45-hour week can have the sum of her time allocated to the different transplant functions add up to 55 hours for that week.

Secondly, a logical look at the global numbers should be taken. For instance, if about one-third of clinic time is spent on post-transplant patients, then the sum of the hours allocated to post-transplant services, as documented on all employee's time sheets, should be equivalent to one-third of the total time reported. Any discrepancies noted should be investigated and corrected or documented as resolved.

Finally, once the time sheets can be certified as correct, they should be reconciled with what is reported on the actual cost report. Shifting of hours or services for ease in cost reports should be completely avoided. If two employees split their time equally between pre- and post-transplant, their time should be reflected on the cost report worksheet as they actually spent the time. In other words, 1.0 FTE should not be allocated to pre-transplant, while the other staff member is allocated to post-transplant, rather than reporting two halves of each. Reimbursement personnel preparing the cost report often are not aware of the impact such simplification can have. If ever audited, it could appear as if the employee allocated as 1.0 FTE, who only recorded 0.5 FTE on pre-transplant functions was over allocated so as to increase cost-based reimbursement. Again, any discrepancies found must either be corrected or have a reasonable and documented explanation.

2. Do We Monitor Space Usage for the Different Phases of the Transplant Program?

Since the costs associated with the lease of space are also included in the calculation of organ acquisition costs on the cost-report, it is extremely important to know how much time the transplant program's space is devoted to pre-transplant patients and to post-transplant patients. Furthermore, for patient convenience, different clinic space may not be used for pre- and post-transplant service, which creates a need to track how the common space is being used.

Specifically, what space needs to be tracked?

If the same set of staff is performing functions for pre- and post-transplant patients combined as described above, and the same clinic rooms and reception areas are being used for pre- and post-transplant patients, then all of the space should be reasonably tracked.

If the space is ever used for non-transplant reimbursable activities, such as research, then that time should be documented as well and removed from the cost report.

How can we track space usage?

As in the example of tracking staff time, the cleanest way to track space usage is to segregate pre- and post-transplant to specific days and/or times. Thereby a clinic visit type ratio can be established that can closely estimate the amount of time the space is devoted to pre-transplant and to post-transplant activities. Large variations in the amount of time the space was devoted to pre- or post-transplant should not be seen from month-to-month; however, the ratio should be reviewed and updated from time to time. As an alternative, total space costs can be allocated based as the ratio of pre-transplant visits to post-transplant visits or other such logical metric.

The systematic method that your Center chooses to determine the space allocation through a combination of fixed clinic days and times and clinic visit ratios should be well documented. This documentation must support the building and occupancy expense allocation submitted on the cost report.

3. Do We Have an Effective System for Determining How to Allocate the Various Non-Staff and Space Expenses of the Transplant Process?

For the same reasons that the staff and space time must be tracked carefully for pre- and post-transplant activities, the non-staff/space expenses should be allocated to the appropriate phase of transplant to ensure that claims and cost reporting activities are true reflections of the operations of the transplant program.

Which non-staff expenses need to be tracked?

The main expenses related to providing transplant patient care other than staff and space include: general office supplies, medical supplies, information systems/communications and pharmaceuticals.

4. Have Our Transplant Program Contracts Been Reviewed by an Outside Party?

Any agreements for the provision of services to the transplant program or by the transplant program that are going to end up in whole or in part on the cost report must fall within the fair market value for those services.

Which type of agreements must be reviewed?

Medical Directorship Agreements, Management Services Agreements, Lease Agreements and Service Agreements.

What terms should we be looking for when having our contracts reviewed?

The transplant program should ensure that any compensation paid (particularly to medical directors) or received (e.g. for space leases) falls within the fair market value for those services. Additionally, if the services provided cover both pre- and post-transplant aspects of the program, then the method of invoicing for the services should clearly include a designation of which services were provided for pre-transplant and which were provided for post-transplant so that only services related pre-transplant/organ acquisition end up on the cost report.

Special attention should be paid to medical directors' compensation based on the qualifications of the director, the level of difficulty of the duties performed, and the actual number of hours actually worked. Specifically, compensation should vary based on the stage of development of the program and the actual duties performed and reported on the monthly logs. Medical directors must track their time. To be safest, typically, medical directorship compensation arrangements should be based on the actual number of hours worked up to a pre-set maximum and documented on logs. Most valuation experts find that medical director compensation tops out at \$150 per hour, although some special circumstances can cause it to be higher on an hourly basis. Pay careful attention to the appearance that more than one medical director is being paid for the same programs.

As always, any lease agreements should also be based on fair market value rent for the specific area and any services that are included.

Conclusion

As recent cases illustrate, there are serious risks associated with reimbursement for organ transplant services. The complex layers of pre- and post-transplant services—including allocation of staffing costs, building and occupancy costs, supply and overhead expenses, and physician costs and the varying services reimbursed—make the compliance challenges all the more difficult. The stakes are too high to let another day pass without assessing organizational procedures in these areas and taking appropriate precautions to ensure compliance.

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Deadline for application of 2004 awards is December 12, 2003

Award	Eligibility	Years	Amt Per Year
ASTS-Novartis Fellowship in Transplantation	Qualified surgeon who will have completed an approved ACGME residency program or its foreign equivalent in a major surgical discipline by 7/1/04	2	\$42,500
ASTS - Fujisawa,USA Faculty Development Award: 1 recipient	Junior Faculty Member - 0-5 Years Post Fellowship	2	\$35,000
ASTS - Roche Laboratories Surgical Scientist Scholarship: 2 recipients per year	Surgical Resident PGY 3	2	\$35,000
ASTS - Thoracic Surgery Fellowship	Thoracic Surgical Resident or Fellow	2	\$42,500
ASTS - Wyeth Mid Level Faculty Research Award	Assistant or Associate Professor and Attendant Appointment	2	\$35,000
Roche Presidential Travel Award: 2 recipients per year	Investigator-42 years of age or younger	1	\$10,000
ASTS Collaborative Scientist Research Award	ASTS Member and collaborating scientist (member or non-member)	2	\$42,500
ASTS Vanguard Prize (4 awards annually)	ASTS Member; Instructor or Assistant Professor	1	\$1,000 & Expenses to ASTS Winter Symposium
ASTS - NKF Folkert Belzer MD Research Award: 1 Recipient	Surgical Resident PGY 3	2	\$35,000

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UNIVERSITY OF WESTERN ONTARIO LONDON HEALTH SCIENCES CENTRE

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Baburao Koneru, MD, Director, Liver Transplantation Program Stanley S. Bergen Building, Room GA230 65 Bergen Street Newark, NJ 07107 ● Liver

ALBANY MEDICAL COLLEGE

ALBANY MEDICAL CENTER HOSPITAL

David J. Conti, MD Director of Transplantation 43 New Scotland Avenue, A-61GE Albany, NY 12208-3478
PH: 518-262-5614 FAX: 518-262-5571 ■ Kidney

STATE UNIVERSITY OF NEW YORK

HEALTH SCIENCE CENTER AT BROOKLYN (SUNY)

Bruce G. Sommer, MD, FACS Professor and Director Division of Transplantation Department of Surgery 450 Clarkson Avenue, Box 40 Brooklyn, NY 11203-2098
PH: 718-270-1898 FAX: 718-270-4789 ■ Kidney ● Liver

MOUNT SINAI MEDICAL CENTER

Charles M. Miller, MD Alfred and Florence Gross, Professor of Surgery, Director, Recanati/Miller Transplantation Institute The Mount Sinai Hospital, Box 1104, One Gustave L. Levy Place New York, NY 10029-6574
PH: 212-241-0106 FAX: 212-996-9688 ■ Kidney ● Liver

NEW YORK PRESBYTERIAN HOSPITAL

Milan Kinkhabwala, MD (Liver) Associate Professor Mark Hardy, MD (Kidney) Professor and Director Kinkhabwala: Center for Liver Disease and Transplantation PH 14 622 West 168th Street New York, NY 10032 Hardy: Kidney Transplant Program 177 Fort Washington Avenue New York, NY 10032
PH: 212-305-9381 FAX: 212-305-9139 ■ Kidney
PH: 212-305-5502 FAX: 212-305-6837 ● Liver

ASTS Fellowship

American Society of Transplant Surgeons

NEW YORK UNIVERSITY MEDICAL CENTER

Lewis W. Teperman, MD Director of Transplantation Mary Lea Johnson Richards Transplant Center 403 E 34th Street, 3rd Floor New York, NY 10016

PH: 212-263-8134 FAX: 212-263-8157 ■Kidney ●Liver

STATE UNIVERSITY OF NEW YORK AT STONY BROOK

Wayne C. Waltzer, MD, FACS Director, Transplantation Services University Hospital and Medical Center at Stony Brook HSCT-19, Room 040 Stony Brook, NY 11794-8192

PH: 631-444-2209 FAX: 631-444-3831 ■Kidney

UNIVERSITY OF CINCINNATI

E. Steve Woodle, MD Professor of Surgery Director of Transplantation Division, University of Cincinnati Medical Center 231 Albert Sabin Way P.O. Box 670558 Cincinnati, OH 45267-0558 Woodle:

PH: 513-558-6001 FAX: 513-558-7040 ■Kidney ●Liver

THE CLEVELAND CLINIC FOUNDATION

Andrew C. Novick, MD Director, Transplant Program Chairman, Dept. of Urology 9500 Euclid Avenue Cleveland, OH 44195

PH: 216-444-5584 FAX: 216-444-9375 ■Kidney

THE CLEVELAND CLINIC FOUNDATION

Delos Cosgrove, MD, Director, Thoracic Transplant Program 9500 Euclid Avenue Cleveland, OH 44195

PH: 216-444-0648 FAX: 216-445-4272 ♥Heart ▲Lung

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Ronald M. Ferguson, MD, PhD Director, Division of Transplantation Room 363, Means Hall 1654 Upham Drive Columbus, OH 43210-1250

PH: 614-293-6322 FAX: 614-293-4541 ■Kidney ●Liver ★Pancreas

ALBERT EINSTEIN MEDICAL CENTER

Cosme Manzarbeitia, MD, FACS Chairman, Division of Transplantation 5501 Old York Road Philadelphia, PA 19141

PH: 215-456-4985 FAX: 215-456-8058 ■Kidney ●Liver

HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

Abraham Shaked, MD Director, Penn Transplant Center 4 Silverstein 3400 Spruce Street Philadelphia, PA 19104-4283

PH: 215-662-6723 FAX: 215-662-2244 ■Kidney ●Liver

UNIVERSITY OF PENNSYLVANIA

Bruce R. Rosengard, MD, Director of Heart-Lung Transplantation Division of Cardiothoracic Surgery 3400 Spruce Street, 6 Silverstein Philadelphia, PA 19104

PH: 215-662-4765 FAX: 215-349-5798 ♥Heart ▲Lung

UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE

John J. Fung, MD, PhD Chief, Division of Transplant Surgery Thomas E. Starzl Transplantation Institute 3601 Fifth Avenue, 4th Floor Falk Clinic Pittsburgh, PA 15213

PH: 412-648-3200 FAX: 412-647-5480 ■Kidney ●Liver ★Pancreas

HOSPITAL ESPANOL AUXILIO MUTUO DE PUERTO RICO

Eduardo A. Santiago-Delphin, MD Director, Transplant Program Box 1227 San Juan, PR 00919

PH: 787-765-7650 FAX: 787-766-4038 ■Kidney

MEDICAL UNIVERSITY OF SOUTH CAROLINA

Prabhakar Baliga, MD Associate Professor of Surgery 171 Ashley Avenue Charleston, SC 29425-0777

PH: 843-792-4003 FAX: 843-792-3553 ■Kidney ●Liver ★Pancreas

UNIVERSITY OF TENNESSEE

A. Osama Gaber, MD Professor of Surgery Chief of Transplant Division 956 Court Avenue A202 Memphis, TN 38163

PH: 901-448-5924 FAX: 901-448-7208 ■Kidney ●Liver ★Pancreas

BAYLOR UNIVERSITY MEDICAL CENTER

(see Dallas Liver Transplant Program below)

DALLAS LIVER TRANSPLANT PROGRAM

BAYLOR UNIVERSITY MEDICAL CENTER

Goran Klintmalm, MD, PhD. (Adult Division) Director, Dallas Liver Transplant Program Chairman, Baylor Institute of Transplant Sciences Department of Surgery 3500 Gaston Avenue Dallas, TX 75246

PH: 214-820-2050 FAX: 214-820-4527 ■Kidney ●Liver

UNIVERSITY OF TEXAS SOUTHWESTERN

MEDICAL CENTER AT DALLAS

Shujun Li, MD Chairman, Division of Surgical Transplantation 5323 Harry Hines Boulevard Dallas, TX 75390-9031

PH: 214-648-4823 FAX: 214-648-4784 ■Kidney

UNIVERSITY OF TEXAS MEDICAL BRANCH GALVESTON

Kristene K. Gugliuzza Director, Transplant Program Department of Surgery E 36 Galveston, TX 77555-0536

PH: 409-772-2412 FAX: 409-772-6368 ■Kidney

BAYLOR COLLEGE OF MEDICINE

Philip Seu, MD Director, BCM Liver Transplantation 6550 Fannin, Suite 1661 Houston, TX 77030

PH: 713-798-8355 FAX: 713-798-8460 ■Liver

Programs 2003

■ Kidney ● Liver ★ Pancreas ♥ Heart ▲ Lung

UNIVERSITY OF TEXAS MEDICAL SCHOOL AT HOUSTON

Barry D. Kahan, PhD, MD Professor and Director Division of Immunology and Organ Transplantation 6431 Fannin, Suite 6240 Houston, TX 77030

PH: 713-500-7400 FAX: 713-500-0785 ■ Kidney

TEXAS TRANSPLANT INSTITUTE METHODIST SPECIALTY AND TRANSPLANT HOSPITAL

Francis H. Wright, MD Director, Organ Transplantation 8201 Ewing Halsell San Antonio, TX 78229

PH: 210-575-8500 FAX: 210-575-8506 ■ Kidney

UNIVERSITY OF VIRGINIA HEALTH SCIENCES CENTER

Timothy L. Pruett, MD Professor of Surgery Chief, Transplantation Surgery Department of Surgery PO Box 800709 Charlottesville, VA 22908-0709

PH: 804-924-9462 FAX: 804-924-5539 ■ Kidney ● Liver

MEDICAL COLLEGE OF VIRGINIA

Marc P. Posner, MD, FACS Professor and Chairman Division of Transplantation Surgery Director, MCV Transplant Program PO Box 980057 Richmond, VA 23298

PH: 804-828-9298 FAX: 804-828-4858 ■ Kidney ● Liver

UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE (SEATTLE)

James D. Perkins, MD, FACS Professor of Surgery Director, Division of Transplantation Department of Surgery 1959 N.E. Pacific Street Box 356410 Seattle, WA 98195-6410

PH: 206-543-3825 FAX: 206-543-8136 ■ Kidney ● Liver ★ Pancreas

UNIVERSITY OF WISCONSIN-MADISON SCHOOL OF MEDICINE

Hans W. Sollinger, MD, PhD Professor and Chairman Division of Organ Transplantation Department of Surgery 600 Highland Avenue Madison, WI 53792-7375

PH: 608-263-9903 FAX: 608-263-7652 ■ Kidney ● Liver ★ Pancreas

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2004 ASTS Course on the

FUNDAMENTALS OF CLINICAL RESEARCH IN TRANSPLANTATION

Scottsdale, AZ

January 22-23, 2004

This Mini-Symposium aims to teach fundamental methodology of designing and conducting clinical trials in transplantation. Instruction and interaction will focus on how to

- develop concepts and skills to design and implement clinical research/clinical trials in transplantation;
- assemble the appropriate research components to complete clinical research / clinical trials in transplantation
- identify possible and appropriate funding mechanisms;
- disseminate research results through publication.

Specific objectives include:

- 1) To provide investigators in the field of transplantation with the concepts necessary to develop a protocol for a clinical trial that is fundable by a peer-reviewed agency;
- 2) To understand the design and implementation issues unique to performing trials in transplantation; and
- 3) To foster collaborative efforts necessary to conduct a clinical trial.

SESSIONS:

- Why Do Clinical Research?
- Overview of Study Design: Strengths and Weaknesses
- Advancing Surgical Techniques
- Clinical Trial Design
- Selecting Endpoints: Critical Choices
- Registry Data: Pros and Cons
- Regulatory Alphabet Soup: IRB, FDA, HIPAA . . .
- Who Might Fund My Study?
- The Anatomy of Funding Proposals
- Successful Trial Administration: From Budget to Personnel
- The NIH
- The Pharma Interaction
- Investigator-Initiated Pharma-Sponsored Research
- Publication / Patents / Proprietary Right
- Ethics of Clinical Research
- Breakout Sessions and Proposal Reviews

For registration information please go to: www.asts.org


ASTS 2004 Winter Symposium

“Surgical Challenges in Transplantation”

ASTS will be conducting its 4th Annual State of the Art Winter Symposium on January 23-25, 2004 at the Marriott Mountain Shadows Resort and Golf Club in Scottsdale, Arizona.

The program will be on “Surgical Challenges in Transplantation.” The members of the planning committee are Sandy Feng, Osama Gaber, Elizabeth Pomfret, Thomas Fishbein and Abhinav Humar.

The Marriott Mountain Shadow Resort and Golf Club is set on seventy acres of desert paradise, with picturesque gardens, lush fairways, and endless variety. Tucked away in the pastel-tinted shadows of Arizona’s Camelback Mountain, you’ll discover a relaxed elegance and unparalleled convenience. Luxurious guest rooms with spectacular views, and unlimited recreation. Extraordinary options for indoor and outdoor dining, and so much more - all just minutes from Phoenix, and less than 12 miles from Sky Harbor International Airport. You can view the Marriott Mountain Shadow Resort and Golf Club at www.mountainshadow.com

More detailed information and registration materials will appear on the ASTS website at www.ast.org 

ASTS 2004 Winter Symposium

SEVENTH INTERNATIONAL CONGRESS

J. Working Committee, M.D., Ph.D.

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University of Colorado

Reginald Barker, M.D.

Professor of Surgery & Abdominal
Surg. Director of Transplantation

Chief, Division of Surgery

University of Maryland School of Medicine

Emilio Barlow, M.D., Ph.D.

Assistant Professor of Surgery, Gastroenterology

& Immunology

University of North Carolina

Walter Chang, M.D.

Professor of Surgery

School of Hospitalized Surgery & Liver
Transplantation

Hospital, Mount Sinai-Montefiore, Park, IL

Anthony Chikudate, M.D.

Professor of Surgery

Executive Director, Organ Transplant
Department

University of Minnesota

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Professor of Surgery

Harvard Medical School

Boston, Massachusetts

Shigehiko Hara, M.D., Ph.D.

Professor of Surgery

Harvard Medical School

Boston, Massachusetts

John Horgan, M.D., Ph.D.

Assistant Professor of Surgery

Mount Sinai Medical Center

New York, NY

Thomas Hoshino, M.D.

Assistant Professor of Surgery

Harvard Medical School

Boston, Massachusetts

Shigehiko Hoshino, M.D., Ph.D.

Professor of Surgery

Harvard Medical School

Boston, Massachusetts

Shigehiko Hoshino, M.D., Ph.D.

Professor of Surgery

Harvard Medical School

Boston, Massachusetts

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Assistant Professor of Surgery

Harvard Medical School

Boston, Massachusetts

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Assistant Professor of Surgery

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Boston, Massachusetts

Shigehiko Hoshino, M.D., Ph.D.

Assistant Professor of Surgery

Harvard Medical School

Boston, Massachusetts

ASTS 2004 Winter Symposium

SPECIAL FEATURE: ASTS COURSE ON Fundamentals of Clinical Research in Transplantation

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COURSE description

This course aims to teach fundamental methodology of designing and conducting clinical research/trials in transplantation. Instruction and interaction will focus on how to:

1. Develop concepts and skills to design and implement clinical research/clinical trials in transplantation.
2. Acquire the appropriate transplantable to complete clinical research/clinical trials in transplantation.
3. Identify possible and appropriate funding mechanisms.
4. Disseminate research results through publications and identify issues such as patents and proprietary rights.

Target Audience: Transplant Physicians, Surgeons, Transplant Coordinators, and Nurses, particularly those interested in clinical research in the area of solid organ transplantation.

COURSE objectives

The participant will be able to:

1. Discuss the necessity necessary in developing a protocol for clinical research/trials that are feasible by a peer-reviewed agency.
2. State the design and implementation issues unique to performing clinical research/trials in transplantation.
3. Develop collaborative elements necessary to conduct a clinical trial.

COURSE sessions

THURSDAY | January 22

9:00 AM - 5:00 PM



FRIDAY | January 23

7:30 AM - 5:00 PM



AMA/continuing education

The American Society of Transplant Surgeons (ASTS) is accredited by the American Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

AMA PRA: The ASTS designates this educational activity for a maximum of 2.5 category 1 credits towards the ASTS Physician Recognition Award. Only physicians are eligible for credit and credit is only given to the extent.

Transplant Coordination: Category 4 Continuing Education Points for Transplant Coordination (CCEPC) have been applied for through the American Board of Transplant Coordination (ABTC).

Maintaining Credits: The program is co-sponsored by American and American Society of Transplant Surgeons. Therefore, 50 hours, MN, is approved as a provider of continuing education for nursing by the Wisconsin Nurses Association Continuing Education Approval Program Committee, which is not related to an approval of continuing education for nursing by the American Nurses Credentialing Center's Commission on Accreditation. Issuance of 2.5 credit hours.

Come Celebrate
ASTS's

**30th Anniversary
to take place at the
American Society of Transplant Surgeons'
4th Annual Winter Symposium
“Surgical Challenges in Transplantation”**

**January 23-25, 2004
Marriott Mountain Shadow Resort and Golf Club
Scottsdale, AZ**

ASTS NEW members

Andrey E. Belous, MD PhD
Vanderbilt University School of Medicine

Bradley H. Collins, MD
Duke University Medical Center

Meelie A. Debroy, MD
University of Michigan Health System

Jonathan A. Fridell, MD
Indiana University School of Medicine

Scott R. Johnson, MD
Beth Israel Deaconess Medical Center

Mercedes S. Mandell, MD PhD
University of Colorado Health Sciences Center

Martin A. Marachio, MD
University of Michigan Health System

Alejandro Mejia, MD
University of Nebraska Medical Center

Jang Il Moon, MD
University of Miami School of Medicine

Robert M. Naraghi, MD
Mendez Transplant & Urological Medical Group

Anil S. Paramesh, MD
Saint Luke's Medical Center

Steven R. Potter, MD
Mendez Transplant & Urological Medical Group

Andrew F. Precht, MD
University of California-San Diego

Sasan Roayaie, MD
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Juan R. Sanabria, MD MSc FRCSC
Medical College of Ohio

Edmund Q. Sanchez, MD
Baylor University Medical Center

Mark J. Walsh, MS MD FRCSC
Toronto General Hospital

John K. Wright, Jr., MD FACS
Vanderbilt University School of Medicine

OCTOBER 2003

October 1 - 4, 2003

TRANSPLANT IMMUNOSUPPRESSION 2003:

The Continuing Challenges

Minneapolis, MN

Contact Phone: 612-626-7600

Contact Fax: 612-626-7766

Contact Email: cmereg@umn.edu

Contact Website:

www.med.umn.edu/cme

NOVEMBER 2003

November 4-8, 2003

4TH ANNUAL RACHMIEL LEVINE SYMPOSIUM

Advances in Diabetes Research:

From Cell Biology to Cell Therapy

Universal City, CA

Contact Phone: 800-679-4693

Contact Email: kramos@coh.org

Contact Website: http://levine_symposium.coh.org

November 27-December 1, 2003

7TH CONGRESS OF INTERNATIONAL SOCIETY FOR ORGAN DONATION AND PROCUREMENT (previous ISOS) & 4TH CONGRESS OF ITCS

Warsaw, Poland

Abstract deadline extended to July

1,2003 Go to www.isodp2003.com

Contact Phone: +48 22 8244164

Contact Fax: +48 22 8244163

Contact Email: info@isodp2003.org

Contact Website:

www.isodp2003.org

DECEMBER 2003

December 4-6, 2003

THE CLINICAL AND BASIC SCIENCE OF ISLET TRANSPLANTATION 2003 AND BEYOND

3rd Annual Symposium

Annenberg Center for Health Sciences

Rancho Mirage, CA

Contact Phone: 760-773-4267

Contact Fax: 760-773-4513

Contact Email:

bratterree@annneberg.net

JANUARY 2004

January 22-23, 2004

AMERICAN SOCIETY OF TRANSPLANT SURGEONS Clinical Research in

Transplantation: Getting Started

Marriott Mountain Shadow

Resort and Golf Club

Scottsdale, AZ

Contact Website: www.ast.org

Contact Phone: 1-800-736-6261

January 23-25, 2004

ASTS 4TH ANNUAL WINTER SYMPOSIUM

Surgical Challenges in Transplantation

Marriott Mountain Shadow

Resort and Golf Club

Scottsdale, AZ

Contact Website: www.ast.org

Contact Phone: 1-800-736-6261

ASTS calendar

ASTS Research Bulletin Board

ASTS has developed a “research bulletin board” to enable you to post information about research projects in which you would like additional participants or other input.

The purpose of this bulletin board is to allow investigators to solicit participation from other centers for their clinical trial. It is hoped that this bulletin board will attract enrollment of a sufficient number of patients to statistically power clinical trials.

Please go to **www.asts.org** and click on to “Members Only” section and then click “ASTS Research Bulletin Board.”

Click into the specific organ where your study better belongs or to see any proposal that has been posted.

We encourage you to utilize this site and refer to it on a regular basis to see what has been added and to post studies for which you are seeking input. We hope this tool will help in developing research studies for which Members would like to find collaborators or receive input and advice from other investigators. Both clinical and basic projects are welcomed.

It should be noted that posting of studies on the trials bulletin board does not in any way denote support or sponsorship of the principal investigator or clinical trial by the American Society of Transplant Surgeons. In addition, the American Society of Transplant Surgeons does not vouch for the scientific validity, clinical efficacy, and/or

The site was developed by the ASTS Scientific Studies Committee. 

JOB BOARD

The ASTS Job Board is enhanced further by the addition to the ASTS website, www.asts.org of CV's of ASTS Candidate Members. This is in an effort to facilitate the interactions between graduating fellows and transplant programs with junior position openings. To access the CVs go to www.asts.org, log into the Members Only section and click on Upload/download files.

MULTI-ORGAN TRANSPLANT FELLOWSHIP University of Minnesota Medical School Department of Surgery. Applications are now being accepted for two positions for a two-year advanced ASTS-approved training program in multi-organ transplantation at Fairview University Medical Center. Must be board certified, eligible, or equivalent in general surgery, and hold or be eligible to obtain a State of Minnesota medical license. Responsibilities include 24 months of specialty training in kidney, pancreas, and liver transplantation. Successful candidates will be appointed as full-time yearly renewable non-tenure track Instructors in the Department of Surgery. The start dates are January 2005 and July 2005. *Candidates are immediately needed and encouraged to apply for the January 2005 opening.* The positions will remain open until filled. Applications for future years will also be accepted. To apply, please submit curriculum vitae and bibliography to: Arthur J. Matas, M.D., Professor of Surgery, Director, Transplant Fellowship Program, University of Minnesota Dept. of Surgery, 420 Delaware St. SE, MMC 280, Minneapolis, MN 55455, matas001@umn.edu, The University of Minnesota is an equal opportunity educator and employer. ✂

MULTI-ORGAN TRANSPLANT FELLOWSHIP The Division of Organ Transplantation, Northwestern University Feinberg School of Medicine is seeking highly motivated individuals for its ASTS-approved transplant fellowship beginning July 1, 2004. The fellowship is a two-year program with training in kidney, pancreas, and liver transplantation and multi-organ cadaver procurement. Comprehensive training in adult and pediatric renal and liver transplantation will be provided. Training will also be provided in laparoscopic living-donor nephrectomy, living donor liver transplantation, and dialysis access. Participation in ongoing clinical research projects and translational projects within the Division of Transplantation is encouraged. Fellows should be board eligible or board-certified in general surgery. Interested individuals should contact: Joseph R. Leventhal, MD, PhD, Division of Transplantation, Department of Surgery, 675 N. St. Clair Street, Suite 17-200, Chicago, IL 60611, 312-695-1703 — Phone, 312-695-9194 — Fax, Email: jleventh@nmh.org ✂

ACADEMIC TRANSPLANT SURGEON Southern Illinois University School of Medicine has a faculty position available for a second transplant surgeon for their longstanding kidney and pancreas transplant program. The successful candidate will be committed to clinical excellence, research and teaching. The opportunity exists to practice general surgery and vascular access in addition to transplantation. The candidate must be board eligible or board certified. Springfield, Illinois is the capital city and offers many of the opportunities associated with a larger city while providing the friendly atmosphere of a small, Midwestern town. This position has been designated security-sensitive, and employment is contingent upon the result of a criminal background investigation. Illinois licensure is a requirement of employment. Send letter of application along with your curriculum vitae to Tim O'Connor, M.D., Department of Surgery, P. O. Box 19638, Springfield, IL 62794-9638. Applications should be received by July 30, 2003 but may be accepted until the position is filled. SIU School of Medicine is an Equal Employment Opportunity/Affirmative Action employer. ✂

THE CENTER FOR SCIENTIFIC REVIEW (CSR) at the NIH is expanding and reorganizing its scientific review structure into four Divisions, including a Division of Clinical and Population-based Studies. CSR is seeking a Director for this division with experience and knowledge in clinical research and/or behavioral and social science, who can serve as an effective liaison with these research communities. This is a senior executive level position. For more information, please see ad at <http://www.csr.nih.gov/employment>, or contact Ms. Pam Sullivan, SullivanP@csr.nih.gov ✂

TRANSPLANT SURGEON: The University of Kentucky Transplant Section wishes to recruit a transplant surgeon at the Assistant Professor level with expertise in performing liver, kidney and pancreas transplantation. Candidates with laparoscopic donor nephrectomy experience will be given special consideration. Please contact: Dinesh Ranjan, M.D., Chief—Transplant Section, 859-323-4661 or dranj1@pop.uky.edu. The University of Kentucky is an Equal Opportunity Employer. Minorities and women are encouraged to apply. ✂

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