

# chimera



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PUBLISHED QUARTERLY FOR MEMBERS OF  
**AMERICAN SOCIETY OF TRANSPLANT SURGEONS**

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



Dear Colleagues:

We have seen considerable progress since the last issue of the *Chimera* and I'd like to share some of this information with you.

Fifty additional members have joined us since last February and we extend them a warm welcome. We now recognize 41 members of the Thoracic transplant community as new ASTS members.

The Awards Committee added three new awards (discussed in our last *Chimera*) directed toward collaborative research, mid level faculty development, and thoracic surgery faculty. Tom Peter's committee has received 43 applications this year which represents an all-time high in award applications.

Dr. Ken Drazen and the Vanguard Committee provided an outstanding venue in Sawgrass, Florida, for the first ASTS Winter Symposium. The symposium, Living Related Kidney and Liver Transplantation, was very well attended, yet the group was small enough to facilitate open discussion. Our planned program for next winter concerns the effect of ischemia and reperfusion on organ and cellular transplantation. We anticipate another lively and informative meeting.

Finally, we have seen change in leadership of Health and Human Services with the appointment of Mr. Tommy Thompson. Formerly the governor of Wisconsin, he has been a major advocate for organ donation and transplantation and has indicated that increased organ donation will be a major theme of his stewardship of this agency. Dr. Sayegh and I have invited him to address the transplant community at Transplant 2001 and we are hopeful that he will be joining us.

I look forward to seeing you in Chicago!

Nancy L. Ascher, MD, PhD  
President, American Society  
of Transplant Surgeons

# **ASTS Business Meeting**

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The annual membership business meeting of the  
American Society of Transplant Surgeons will take place:

Monday, May 14, 2001

5:45 p.m.

Sheraton Ballroom 1-3  
Sheraton Hotel and Towers, Chicago , IL

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## **ASTS 2002 Winter Symposium**

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Bench to Bedside: Ischemia/Reperfusion

Injury in Clinical Transplantation

The ASTS Council met February 23, 2001. The following include reports presented at that meeting:

## Awards Committee Update

Thomas Peters, Chairman of the ASTS Awards Committee, reported that the Committee is still refining the descriptions of the various ASTS awards. There were 43 applicants from 29 institutions for this year's ASTS awards program, which is a record number of applications. The application for the year 2002 awards will be on the ASTS website in the near future. 🌐

## Scientific Studies Committee Update

Committee Chairman, Paul Kuo, reported that one of the activities of the Scientific Studies Committee was contact with NIH regarding grants for individual sites for research coordinators to pull samples that individual studies may be interested. The Committee is also addressing redefining endpoints. Dr. Kuo has contacted the FDA and they are interested in a project of redefinition of endpoints. He will next look into the possibility of conducting a conference on this topic. 🌐

## Standards on Organ Procurement Committee Update

Jean Emond and the Committee reported that with respect to the split liver registry, ASTS is supporting a web based electronic survey instrument which will be used to collect data from centers performing split livers. The database will automatically update overall series as cases are entered and make summary data available to all contributors in appreciation for their input. There will be a general session on this topic at Transplant 2001 and the Committee will hold a meeting in Chicago during the Transplant 2001 meeting. 🌐

## Thoracic Organ Transplantation Committee Update

CURRENT ISSUES IN CARDIOTHORACIC TRANSPLANTATION SYMPOSIUM: The American Society of Transplant Surgeons and the Society of Thoracic Surgeons jointly sponsored the first "Issues in Cardiothoracic Transplantation" Symposium held in conjunction with the Society of Thoracic Surgeons meeting in New Orleans this winter. The symposium was co-chaired by David Follette, MD representing the ASTS and Fred Grover, MD from the STS. The meeting was well attended and extremely well received.

Four critical issues in thoracic transplantation were addressed. The first speaker was Fred Grover, MD, Chairman of the UNOS Thoracic Committee, who gave the symposium participants an update on the implementation of the new rule and some of the critical issues that UNOS has been addressing regarding allocation of both hearts and lungs. During the panel discussion a number of questions were directed to Dr. Grover regarding changes in allocation policies for not only hearts but also for lung transplant recipients and the implementation of a potential needs listing in lung transplants similar to heart transplantation. Both Dr. Grover and Dr. Patterson have excellent comments in this regard.

Dr. Bruce Reitz then addressed recent developments in chronic graft loss. He gave an excellent summary of the endothelial changes that occur in both heart and lung chronic grafts and new ways that these are being treated with their implications. He also gave a nice review of the long-term results in both heart, lung and heart/lung transplantation. ►

Bruce Rosengard then gave a superb review of the pharmacology and uses of new drugs utilized in thoracic transplantation. He also gave insight into several ongoing clinical trials looking at the pharmacology of Rapimmune and other new agents that are in the developmental stages.

Lastly, Alec Patterson addressed the issue of donor management in lung transplantation and the need to increase the total donor pool. He shared with the participants the strategies utilized at the Washington University in St. Louis for increase in the total number of donors. During the panel discussion there was much talk about the use of donor teams to evaluate potential donors and then shipping these organs to transplant centers. This strategy could be developed and would decrease the cost of harvesting and may result in significant timesaving and shorten ischemic time. The four speakers then participated in a panel discussion.

We are beginning plans to develop next year's symposium and will be working very closely with the Society of Transplant Surgeons to develop mutual topics of interest. 🌐

## ASTS Website Update

The ASTS Website at [www.ast.org](http://www.ast.org) has a Job Board. All Members are encouraged to send positions available at their institutions to be posted. Positions will also be placed in the *Chimera*. To submit a position to the Job Board please go to the ASTS website. 🌐

## ASTS Scientific and Government Liaison Update

### ASTS continues to participate in UNOS Medical Examiner and Coroner Task Force

The United Network for Organ Sharing (UNOS) reconvened the national Medical Examiner and Coroner Task Force in early 1999. The original task force was created in 1993 through the efforts of the National Association of Medical Examiners (NAME) and the Association of Organ Procurement Organizations (AOPO). ASTS was one of the charter members of the task force and has continued to be represented on the task force. Goran Klintmalm, MD, PhD was the original appointee to the task force and has remained the ASTS representative throughout the group's evolution.

Initially, the task force met and was fostered by immense support from the medical examiner/coroner and donation communities. The task force set the stage for open dialogue among members of these professional groups. Its work ultimately resulted in an increase in release rates of organ donation cases from medical and coroner cases, as well as appropriate preservation of forensic evidence. In 1994, the task force produced a policy statement to facilitate organ and tissue recovery from medical examiner and coroner cases. Each participating organization endorsed the policy statement. (See sidebar on page 8 and 9.)

The task force was less active in the mid-1990s and eventually ceased to meet. At the beginning of 1999, UNOS reconvened the original Medical Examiner and Coroner Task Force with expanded representation. Members of the present task force are:

Mary Fran Ernst and Patricia McFeeley, MD – American Academy of Forensic Sciences  
Duke Kasprisin, MD – American Association of Tissue Banks



Goran Klintmalm, MD, PhD – American Society of Transplant Surgeons  
Frank Delmonico, MD – American Society of Transplantation  
Becky Sayer – Association of Organ Procurement Organizations  
Jeffrey Barnard, MD – At-Large Representative  
Jim Springer – At-Large Representative  
Marcella Fierro, MD and Fritz Lower, MD – College of American Pathologists  
Mary Beth Danneffel, RN, CEBT – Eye Bank Association of America  
Mary Lou Kearns – International Association of Coroners and Medical Examiners  
Catherine Dougherty, RN, MA – International Association of Forensic Nurses  
E. Michael McCann – National District Attorneys Association  
Edmund Donoghue, MD and Tom Hegert, MD – National Association of Medical Examiners  
Stephen Dentel, RN, BSN – North American Transplant Coordinators Organization

The UNOS liaison to the task force and its project director is Gloria Taylor, RN, MA, CPTC.

As a direct result of reconvening the task force, the Centers for Disease Control and Prevention (CDC), the National Association of Medical Examiners (NAME) and the United Network for Organ Sharing (UNOS) collaborated to organize a special scientific session at the 1999 NAME annual meeting that addressed *Organ Donation and Effective Death Investigation: Tensions and Resolutions*. Subsequently, the task force and UNOS assisted with the preparation of a special session for the 2000 NAME annual meeting to address *Tissue Transplantation*.

Through the efforts of the task force, a death investigator and recovery agency resource booklet has been formulated. The contents of this publication includes the task force's policy statement; examples of donation-related medical examiner/coroner state laws; model donation protocols and policies; descriptions of evidence kits and accompanying informational forms; samples of OPO projects related to medical examiners and coroners; and a bibliography of suggested readings. This resource booklet will be printed in 2001 and made available to all organ and tissue recovery organizations, medical examiner offices, and coroner offices of counties with populations of 25,000 or greater.

Exploring mechanisms for improved communication with district attorneys is one of the short-term goals for the task force. The National District Attorneys Association (NDAA) board of directors has agreed to discuss donation-related issues of homicide cases. The task force hopes to foster inroads with this professional group and explore educational opportunities.

Another short-term task force goal includes incorporating organ and tissue donation material into current death investigator training and introducing forensic training for recovery personnel via accessible procurement education sources. To this end, St. Louis University incorporated the content of the resource booklet into their death investigators' course. Progress has been made with the American Board of Medicolegal Death Investigators, Inc. to incorporate organ and tissue donation questions on their certification exam. Two NAME members gave a presentation at the 25th Anniversary NATCO Meeting in Orlando, Florida in August 2000. Initial conversations have taken place with ASTS regarding the possibility of providing some type of certification course for transplant surgeons and fellows.

Due to the task force's efforts, two areas of the nation have launched new initiatives. In Cook County, Illinois, the Chief Medical Examiner developed a protocol to release every donor, every time. The protocol requires that the recovery agency ascertain the family's willingness to donate prior to contacting the medical examiner for permission. In Colorado and Wyoming, the organ and tissue recovery agency is also

collaborating with their coroners to provide information regarding the family's donation wishes concerning potential donation cases that fall under their jurisdiction. These collaborative efforts are proving very successful. Cook County, Illinois, has released 100% of cases for donation under this new initiative.

The task force's most recent deliberations have been regarding the non-heartbeating donor. The task force will meet during 2001 to confirm the next steps for their initiatives and to finalize the non-heartbeating donor statement. ❧

## **Policy Statement to Facilitate Organ and Tissue Recovery: Medical Examiner/Coroner Cases**

A working group of representatives from the National Association of Medical Examiners and the principal national transplant organizations convened to review the medical examiner/coroner's role in the provision of human organs and tissue for transplantation.

### **IT WAS RECOGNIZED:**

- 1) Medical examiner/coroner cases constitute the single greatest source for healthy organs and tissue donation.
- 2) There is generally good cooperation and support from the medical examiners/coroners across the United States. There is apparent variability in the level of cooperation and support of medical examiners/coroners from jurisdiction to jurisdiction and there remains significant opportunity to continue to improve the number of organs and tissues for transplantation.
- 3) On occasion, there are individual cases where permission for transplant agencies to pursue potential organ or tissue donation may be denied by medical examiners/coroners because of their legal and medical mandate to determine cause and manner of death and investigate related circumstances.

### **IMPROVEMENT:**

Key issues were identified to overcome existing barriers toward the improvement of the potential donation of organs and tissues from medical examiner/coroner cases in the United States. Each representative was asked to solicit from their organizations an endorsement of the provisions below in an effort to reach an initial consensus enabling further examination of these issues and promote improvement in the provision of needed organs and tissues.

- 1) It will be very beneficial to develop and promote national guidelines acceptable to the representative national basic guidelines will facilitate the organizations. These establishment of specific protocols on a local level.
- 2) Local cooperation and support is strongly encouraged. Establishment of local protocol consistent with the above national guidelines should be developed through the cooperative effort



of the medical examiner/coroner office, procurement agencies, state and district attorney offices and local law enforcement. Compelling legislation is strongly discouraged.

- 3) Using the established guidelines, there should be no compromise to the quality practice of forensic medicine.
- 4) To the extent that state or municipal funds are not available to medical examiner/coroner offices to support organ and tissue donation activities, it is appropriate for reimbursement to be made. This reimbursement should be in a form that would not compromise, or even give the appearance of compromising, the objectivity and independence of the medical examiner/coroner office, the transplant agencies or their staff or agents.
- 5) Local and national educational and liaison activities should be established for the continued success and improvement of the provision of needed organs and tissues from medical examiner/coroner offices. 📞

## ASTS

## “THANKS”

**Founders Category:**

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### WASHINGTON UPDATE

**T**he first quarter of 2001 has already proven that this will be a productive and exciting year for ASTS. The Society has been actively involved in organ donation efforts, HCFA's tissue typing regulation, and the fiscal year (FY) 2002 appropriations process which sets the level of federal funding for government agencies that address transplantation research and services. ASTS will continue to play a leadership role on organ transplantation and related issues as 2001 evolves.

#### Organ Donation

**The Administration:** The new Secretary of Health and Human Services (HHS), Tommy Thompson, announced on February 9 his intent to launch a new national effort to encourage organ donation during the first 100 days of his tenure at HHS. Soon after this announcement, ASTS spearheaded an effort to bring together a group of transplant-related organizations to develop a set of consensus organ donation recommendations in an attempt to assist Secretary Thompson in his effort to significantly increase the rate of organ donation in the United States.

This effort culminated in a set of proposals that was forwarded to Secretary Thompson and, according to subsequent conversations with HHS officials, was well-received by the new Administration. The proposals were supported by ten national transplant-related organizations, including the ASTS, the American Association for the Study of Liver Diseases, the American Association of Tissue Banks, the American Liver Foundation, the American Society of Pediatric Nephrology, the American Society of Transplantation, the Association of Organ Procurement Organizations, the Juvenile Diabetes Research Foundation, International, the National Kidney Foundation, and

Transplant Recipients International Organization, Inc.

This package of proposals contained a range of initiatives designed to meaningfully increase the rate of organ donation in the United States. These proposals range from funding staff positions for organ coordinators (who would be responsible for coordinating organ donation and recovery at a hospital or group of hospitals) to the enactment of a federal law to honor a donor's consent to donate his or her organs based on the existence of an organ donor card or other credible evidence of intent to donate one's organs, regardless of familial objections. These recommendations should prove useful to the secretary as he con-

## **ASTS will continue to be a leader in the organ donation debate and an active participant in Secretary Thompson's efforts to increase the nation's supply of organs.**

tinues to develop his strategy, and ASTS and other transplant organizations stand ready to serve as a resource to HHS as it moves forward with its organ donation initiative.

The importance of these efforts to increase the supply of organs was underscored by a recently released UNOS report citing increased need for organ donation. According to the 2000 Annual Report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network, between 1990 and 1999, the number of Americans awaiting organ transplants more than tripled from 21,914 in 1990 to 72,110 at the end of 1999. Annual cadaveric and living donor transplants over the same period increased at a far slower rate, moving from 15,009 in 1990 to 21,715 in 1999.

**The House:** The U.S. House of Representatives and Senate have also identified organ donation as an early legislative priority of the 107th Congress. On March 7, the House unanimously passed H.R. 624, the Organ Donation Improvement Act of 2001. H.R. 624 contains the organ donation provisions that were included in last year's House-passed NOTA reauthorization bill, which ultimately was not enacted. Specifically, the bill:

- recognizes the importance of families discussing organ donation and the importance of living organ donation;
- authorizes the secretary to award grants to states, OPOs, and non-profit private entities

for the purpose of subsidizing travel and subsistence expenses incurred by living organ donors; and

- provides the Secretary of HHS with the authority to make grants to states for the purpose of carrying out activities and programs designed to increase the number of organ donors, including living donors.

This bill now awaits action in the U.S. Senate. Rep. Jay Inslee (D-WA) also reintroduced two transplant-related bills that he first introduced in the 106th Congress. H.R. 953, the Organ Coordination Improvement Act, would create federal grants for hospitals, networks of hospitals, and OPOs to hire organ donation coordinators. Congressman Inslee's other bill, H.R. 955, the Organ Donor Enhancement Act, would establish a National Living Donor Registry similar to the National Bone Marrow Registry. The registry would contain lists of biologically unrelated individuals who are willing to be living organ donors.

**The Senate:** Senator Charles Schumer (D-NY) has already introduced an organ donation bill of his own. Sen. Schumer's legislation — the Organ and Tissue Donation Enhancement Act of 2001 — would create a federal database administered and updated by HHS containing basic information on organ and tissue donors throughout the nation. This registry would be national in scope and would combine and coordinate donor information

from state registries with information on donors from across the nation who could sign up to be a donor on a new website established by the bill.

In order to encourage participation in the registry, information promoting organ donation would be included along with people's IRS tax forms, providing information on organ donation, as well as specific instructions on how to access the website and participate in the registry. The bill would also help the 40 states that do not have registries establish them by enabling them to apply for grants of up to \$300,000, which could be used for activities like outreach campaigns.

Finally, the Shumer legislation would establish a new task force of organ donation experts to study ways to improve the registry, increase donations, and promote public awareness. The bill would then authorize a \$15 million, five-year outreach campaign to raise public awareness about the registry.

Other legislators are considering the introduction of organ donation bills as well. Senator Durben (D-IL) is poised to introduce a registry bill of his own and has been working with transplant-related organizations, including ASTS, on the specific language of the bill. How these and other legislative alternatives progress over the next several months and what is actually enacted into law is not clear at this time. ASTS will continue to closely monitor legislative and regulatory developments that impact organ donation and will support meaningful improvements to the organ donation system.

**ASTS will continue to remain in close contact with key members of Congress and their staff as legislative proposals that impact organ donation and other transplant issues continue to be debated in the 107th Congress.**

### **Tissue Typing**

ASTS joined AST and the American Society for Histocompatibility and Immunogenetics (ASHI) on a letter sent in late January, requesting HCFA to delay the mandatory application of its regulation regarding HLA matching and T-cell cross-matching. Under this regulation, all histocompatibility laboratories must comply with the regulations of HLA typing and T-cell cross-matching for all solid organ transplants in order to obtain HCFA certification. Since the entire transplant community has not uniformly performed HLA typing or T-cell cross-matching for heart, lung, or liver transplant recipients, mandatory compliance with this regulation would have a disruptive impact on current clinical practices.

In the letter, ASTS, AST, and ASHI cited the lack of consensus data establishing conclusively whether HLA matching and T-cell cross-matching significantly improves the immediate or long-term outcome of heart, lung, or liver transplants as a reason for not mandating compliance with this regulation. In addition, the groups called for a current review of data with respect to the impact of HLA matching and cross-matching on the outcomes now achieved in the modern era. Finally, the letter requested that the ASTS, AST, and ASHI have the opportunity to present to HCFA with scientific data relevant to the rationale of this regulation.

### **Fiscal 2002 Appropriations**

ASTS submitted testimony for the written record to the House and Senate Appropriations Subcommittees on Labor, Health and Human Services, and Education (Labor-HHS) regarding FY 2002 funding levels for the federal agencies that impact ASTS's members. ASTS testimony focused on the need to increase funding for the various research and services programs at HHS that focus on organ donation and transplantation, particularly at the Health Resources and Services Administration's Division of Transplantation and the National Institutes of Health.

The appropriations process for FY 2002 will be much different than it has been over the past several years. For the first time in over 40 years, a Republican-controlled Congress will be negotiating spending levels with a Republican president. This will change the appropriations dynamic dramatically. The appropriations process during the past several years was characterized by eleventh-hour negotiations between President Clinton and the Republican Congress that often resulted in higher spending levels than what was budgeted by Congress. The process this year will be quite different, as President Bush looks to limit the growth in federal spending as he advocates for his tax cut proposal.

In addition, Rep. Ralph Regula (R-OH) replaced retired Rep. John Porter (R-IL) as chair of the Labor-

HHS Appropriations Subcommittee. Chairman Regula has not been particularly active on health care issues in the past, so his funding priorities are still unclear at this point. However, it is unlikely that his committee will report out a bill that is vastly different from the president's budget, which will be released in early April.

In the Senate, Sen. Arlen Specter (R-PA) will remain chair of the Labor-HHS Appropriations Subcommittee. Chairman Specter has been a long-standing advocate of the bipartisan plan to double the NIH's budget over a five-year period. As this increase was included in President Bush's budget outline which was presented to Congress in February, the likelihood of significant increases in NIH funding for FY 2002 is quite good.

### **NOTA Reauthorization**

As the 106th Congress came to a close, efforts to reauthorize the National Organ Transplant Act lost momentum for a number of reasons. First, UNOS signed a contract with HHS that contains the provisions that former Secretary Donna Shalala was seeking to implement through the issuance of her controversial final rule. Second, Secretary Shalala created an Advisory Committee on Organ Transplantation, which is expected to play much the same role that the Scientific Advisory Committee would have played under the Senate's NOTA reauthorization legislation. (ASTS President Nancy Ascher was subsequently named chair of this important panel.) Finally, a stalemate between the House

and Senate versions of the NOTA bill developed that proved to be insurmountable in the 106th Congress.

At the current time, the Bush Administration and Congress seem content to switch their focus from the highly contentious and divisive organ allocation debate to efforts to increase organ donation. While NOTA reauthorization efforts may resurface during the 107th Congress, no substantive efforts have been made to date.

## Conclusion

ASTS will continue to be a leader in the organ donation debate and an active participant in Secretary Thompson's efforts to increase the nation's supply of organs. ASTS will also continue to remain in close contact with key members of Congress and their staff as legislative proposals that impact organ donation and other transplant issues continue to be debated in the 107th Congress. 2001 is an important year for ASTS members, and ASTS will continue to keep its members well-informed on the constantly changing political and policy developments that occur in our nation's capital. ❧

Prepared by:

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Jeremy Allen, Legislative Director  
Powers, Pyles, Sutter & Verville, P.C.

# JOB BOARD

## ACADEMIC TRANSPLANT SURGEON

Southern Illinois University School of Medicine has a faculty position available for a second transplant surgeon to support Memorial Medical Center's longstanding kidney and pancreas transplant program. The successful candidate will be committed to clinical excellence, research and education. The opportunity exists to practice general surgery or urology in addition to transplantation. The candidate must be board eligible or board certified by their appropriate field. 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 Gary Dunnington, MD, Chair, Department of Surgery, P. O. Box 19638, Springfield, IL 62794-9638. Applications should be received by May 1, 2001 but may be accepted until the position is filled. SIU School of Medicine is an Equal Employment Opportunity/Affirmative Action employer. ❧

## ASSISTANT PROFESSOR/ASSOCIATE PROFESSOR/DIRECTOR ASSISTANT PROFESSOR

Assistant Professor/Associate Professor (Director) and Assistant Professor, both tenure track, full-time salaried faculty positions available at the University of Vermont/Fletcher Allen Health Care. Candidates must have completed a Board approved residency program in general surgery/urology with additional training of at least 12 months in an ASTS accredited program; meet eligibility for VT medical licensure, and possess ability, experience and interest in teaching and academic pursuits. Salary is competitive. Applications accepted until April 15, 2001. Send letter of interest to Dr. Steven Shackford, Chair, Department of Surgery, University of Vermont, Fletcher House 301, MCHV Campus, FAHC, Burlington, VT 05401. The University of Vermont is an Equal Opportunity/Affirmative Action Employer. Applications from women and those from diverse racial, ethnic, and cultural backgrounds are encouraged. ❧

# Mechanical Cardiac Current Appl Future Trial

## **Present Status of Devices for Heart Failure**

Current use of mechanical circulatory support devices is dominated by the indications of post-cardiotomy shock and bridging to cardiac transplantation. In the US, about 6,000 patients a year receive support devices after cardiac surgery, with hospital survival of 20% to 40%. Sustained improvement of native heart function after support also occurs in 5% to 15% of transplant candidates, with greater frequency of recovery in patients with fulminant myocarditis. Bridging to cardiac transplantation occurs in 300 to 400 patients yearly in the US, with an overall discharge rate of 50% to 70% from device implantation through transplantation.

Limitations in our current conception of device indications need to be recognized. First, the need for biventricular versus univentricular support is difficult to determine. Second, the ultimate utility of a total artificial heart versus ventricular assist device(s) (VAD) has not been established. Third, the intended duration of mechanical support is a moving target. The time and type of device utilization is influenced by external factors such as the time to myocardial recovery, donor organ availability, the potential of outpatient therapy and the unpredictability of adverse events associated with new technology. Thus, even within the field of currently used devices, evolving

indications mandate flexible guidelines for utilization.

## **Development of Drugs and Surgical Devices for Advanced Heart Failure**

Observation provided the basis for early therapies of heart failure, many of which have subsequently been abandoned. A systematic approach to testing pharmacologic therapies in heart failure has arisen only within the last 20 years. The basis of evidence supporting the current medical therapy with angiotensin-converting enzyme inhibitors and beta-adrenergic receptor antagonists has arisen from double-blind, randomized controlled trials in hundreds to thousands of patients with mild to moderate heart failure. Except for digoxin, oral inotropic agents have been shown in controlled trials to increase mortality, despite sound theoretical rationale. The template of the double-blind, randomized control trial has emerged as the gold standard for evaluating new pharmacologic therapies. It has not been applied to urgent therapies such as diuretics for relief of pulmonary edema and intravenous inotropic agents for cardiogenic shock (CS), during which placebo therapies might be regarded as unacceptable.

Many surgical approaches have been introduced for heart failure. The coronary artery surgery trial demonstrated benefit in patients with reduced left ventricular ejection frac-

tions (LVEFs) but did not target patients with symptomatic heart failure. Requiring five years to complete enrollment, the trial of revascularization for acute CS demonstrated benefit in patients [gt]75 years of age. Revascularization, valve surgery and other remodeling techniques are being employed for some patients with more severe chronic heart failure (HF). The inability to provide comparable placebo therapy, strong patient preferences regarding invasive procedures, and the front-loaded risk of operative procedures have complicated the evaluation of these new approaches.

## **Fundamental differences between drugs and devices**

As therapies for heart failure advance beyond drugs into procedures and devices, fundamental differences emerge in the evaluation of efficacy. By contrast with drug development, progress with devices is more incremental, with experience leading to progressive device modifications. The impact of devices is more transparent, in part because the most obvious risks are front-loaded compared with those from new drugs. It is harder for the effects of devices to be masked or mimicked by the natural history of heart failure. Practical considerations relate to the higher order of magnitude of expense per patient in a trial, which can be prohibitive for companies without major revenue from previous products. The clinically meaningful benefit,



# Support 2000:

# ications and Design

however, is projected to be larger than the benefit of new drugs, such that estimated sample sizes are in hundreds rather than thousands of subjects. The experience and skill necessary to achieve optimal outcomes restrict center participation in trials and limit the generalizability of results. A crucial difference between drugs and devices is the inability to blind patients or physicians to therapy, a limitation with both ethical and practical implications for clinical trials.

The sum of evidence guiding therapy with drugs is dominated by evidence from large trials completed prior to drug approval. Once it is approved, it is difficult to identify use and attribute effects of any particular drug because of variable prescription, adherence and combination with other medications. For this reason, post-marketing surveillance provides limited information regarding drugs for heart failure, except for non-cardiovascular side effects. By contrast, the very complexity and undisguised impact of devices render their use and outcomes easier to track, as long as appropriate registries are maintained. The cumulative body of evidence guiding the ultimate use of devices may be drawn more from information gained after initial approval.

## **Target Populations and End Points for Mechanical Circulatory Support**

Target populations for mechanical circulatory support can be defined by the

expected natural history of heart failure. Patients with CS have an in-hospital mortality of [lt]50% but also carry high risk for patient-related operative complications. Ambulatory patients without resting symptoms on standard oral therapy often survive for two years or longer. Despite various approaches to risk stratification, it remains hard to specify an intermediate-risk population. For patients receiving outpatient intravenous inotropic therapy, the six-month mortality is currently in the range of 50%. However, without objective indications for and restrictions on this therapy, it may encroach on the population with less advanced disease. Another target population might be cardiac transplant patients with triple vessel coronary artery disease (CAD) and decreased ejection fraction, with [gt]50% one-year survival, but mechanical devices in the post-transplant population may be complicated by previous surgery and immunosuppression. The target population for trials should be defined widely to include patients with the best natural history compatible with the degree of certainty that a given device will provide an improvement. This would be greatly facilitated by a multicenter registry of advanced heart failure. After approval, ongoing re-evaluation of a successful device should reflect the observed trend for downshifting risks, in which procedures with proven benefit in a high-risk population become generalized to patients with less risk of post-operative complications but potentially less benefit.

End points for clinical trials will be chosen according to the severity of disease in the population selected. For patients with the most severe disease, early survival will be a fundamental end point. A combination of early survival and functional end points may be most appropriate for trials allowing eventual device placement in patients randomized to medical therapy. As the risk of death becomes imminent, measurements of functional capacity, quality of life and survival adjusted for patient preferences become increasingly relevant. At all levels, measures of efficacy will need to be supplemented by measures of cost-effectiveness. It should be emphasized, however, that cost-effectiveness for a successful device is likely to improve after approval, as experience is gained and costs are decreased.

## **The Spectrum Including “Breakthrough” Devices**

In the future, initial studies could identify a therapy with such an obvious impact on survival that it would be considered a “breakthrough” for a population with otherwise high early mortality. In retrospect, cardiac transplantation was considered a breakthrough that has been widely accepted without a controlled study. Most new therapies do not enter the breakthrough realm during preliminary testing but fall somewhere else along the spectrum before approval. Outside of breakthroughs, there may be some

therapies that are not yet approved but are considered by experienced clinicians to be so effective that waiting for a controlled trial would not be ethical. The best way to bridge this gap to expedite approval from regulatory agencies has not yet been determined for any of the life-threatening diseases. The focus of this conference is not on the approval process but on designing trials of devices for which there is reasonable doubt regarding efficacy. Even for devices in the breakthrough realm for end-stage disease, the design of trials would remain relevant for extension to those populations with lesser severity of illness, in whom the benefit of the device could not be assumed.

### **Trial Design for Mechanical Circulatory Support**

All new devices are required by the Medical Device Amendments Act to be “safe and effective,” as shown through “well-controlled scientific studies” or “valid scientific evidence.” Because mechanical circulatory support devices fall into the highest of three risk categories, the sponsor must conduct clinical trials before the FDA grants a pre-marketing approval (PMA) decision. Multiple challenges characterize the performance of these trials for mechanical support devices. Because device innovation, exemplified by left ventricular assist devices (LVADs), is incremental and iterative, it is difficult to determine when a device should come to clinical trial and which aspects of development should be “frozen” while modification continues throughout the investigational and post-marketing stages. There is little precedent for trial design when a high severity of illness limits the duration of observation and humanistic concerns dictate consideration of alternate therapies outside protocol. Other life-threatening illnesses, such as cancer and AIDS, have led to consideration of research designs to minimize ethical conflicts and shorten the PMA processes while shifting more emphasis to rigorous post-marketing studies.

The randomized controlled trial (RCT) remains widely regarded as the

most powerful and sensitive tool for comparing therapeutic interventions and the most persuasive force for the acceptance of new technology. Many of the differences between drugs and devices, as detailed in the preceding text, complicate the translation of RCTs from pharmaceutical trials to trials of mechanical support devices.

### **Ethics of Randomized Controlled Trials for Mechanical Circulatory Support**

Special emphasis was placed by this conference on consideration of the ethics of RCTs for mechanical support devices. A fundamental tenet of the ethical RCT is that equipoise exists for the treatment being tested; it would thus not be ethical to do an RCT of a device already determined from initial testing to be in the breakthrough realm for the population being considered. Theoretical equipoise, in which available data and investigator preference are exactly balanced, may in fact never be located for the individual clinician. Clinical equipoise, in which genuine debate and uncertainty exist among the clinical community, is more feasible and relevant. Although it was initially challenged for the REMATCH trial, the position of equipoise was strengthened by the analysis of pilot data from the pilot trial for REMATCH (PRE-MATCH), in which no clear survival benefit from the LVAD could be seen at three months.

After randomization has taken place, the patient and his physician are aware of the selected therapy, unlike participation in the placebo arm of a double-blinded drug trial. The combination of life-threatening disease and unblinded therapy raises ethical issues beyond that of physician equipoise at the start of the trial. The visible impact of the device may threaten maintenance of equipoise for investigators following patients during the course of a trial. Responding as individuals to unfiltered information, patients are less likely to be in positions of equipoise even before randomization. Patients consenting to new trials are likely to be already biased toward the

procedure and thus may perceive randomization to the control arm as a loss of hope, with potentially deleterious impacts on individual outcomes.

### **Practical Issues of Randomized Controlled Trials for Mechanical Circulatory Support**

Patient preference for specific therapies perceived to be life-saving may limit enrollment, particularly when a similar therapy is perceived to be offered by other routes. From a methodologic aspect, randomization does not eliminate evaluation bias when all parties know the treatment received. Patient dissatisfaction regarding treatment choice threatens compliance with follow-up and increases the likelihood of off-protocol therapy that could compromise the trial results, as was seen in early trials of AZT for AIDS.

The cost of initiating a randomized trial for a new device greatly exceeds that of continuing to report uncontrolled experience. For this effort to be undertaken, the ultimate value in terms of acceptance as an effective device must be consistently endorsed. Financial impediments have profoundly impaired the conduct of clinical trials of devices, for which there have been substantial unreimbursed costs. These disincentives to enrollment increase the duration and overall cost of the study, delaying the time to potential recovery of development costs. Government support for reimbursement of routine Medicare treatment costs and “conditional coverage” of treatment costs in recognized scientifically-designed trials are strongly endorsed by this conference.

Despite a number of obstacles, an RCT of classical design is nearing completion to determine the impact of an implantable mechanical circulatory support device as destination therapy compared with optimal medical therapy. If the REMATCH trial proves a survival benefit for devices in this population, similar devices may be tested against this benchmark. Regardless of the outcome of this trial, both the lessons learned during

its conduct and the ultimate results will have a profound influence on the design of future trials.

## **Modifications of the Randomized Controlled Trial for Mechanical Cardiac Support**

It should be recognized that the gold standard methodology for evaluating the impact of a treatment on outcome remains the randomized, double-blinded, placebo-controlled trial. It should also be recognized, however, that surgical interventions in advanced illness may not appropriately lend themselves to all aspects, such as blinding, of this methodological gold standard. With increasing appreciation for the unique aspects of mechanical circulatory support for advanced heart failure, variations in the design of randomized trials merit consideration.

The aspects of randomization and a control arm can be retained in a non-blinded trial with an option to receive active device therapy as “compassionate use” after the achievement of a pre-defined time or intermediate end points. (Because only the original cohorts would be compared, this does not represent a true crossover design.) This feature may encourage recruitment and retention, while re-aligning incentives for the patient and physician to continue full efforts after randomization to a control arm. Models for randomized trials that allow some degree of patient preference could improve recruitment and patient satisfaction while providing more information on outcomes for patients not desiring device therapy. The degree to which patient preference should influence the choice of therapy remains a major ethical issue for this and other life-threatening conditions. From a more practical standpoint, it is not clear to what extent the advantages of design modifications would outweigh the increase in sample size that would be required.

## **Comparison of Non-randomized Cohorts**

In the absence of a randomized control group, there are no large historical

groups that could be considered for comparison. Contemporary cohort studies offer better information than observational reports without comparison, but they are compromised by a major bias in favor of new treatments. Data provided by a cohort analysis of the bridge-to-transplant experience indicated a major benefit from the device for that indication. While this cohort data were often cited to suggest that a randomized trial of therapy in non-transplant candidates was not ethical, its relevance to this different population was questioned when the small randomized pilot trial indicated no major difference in early outcomes between the device and optimal medical therapy.

Alternatively, to generate prospective control groups, cohorts could be defined by an obligatory control period prior to enrollment that could provide short-to-intermediate-term information, after which, however, subjects entering surgery might be either better or worse than at initial evaluation. Comparison of patients preferring surgery to patients preferring medical therapy would require an extensive adjustment for baseline factors influencing outcome, not all of which can be identified. For non-randomized cohorts, it is not possible to adjust for all of the factors that lead to the provision of a therapy to one patient and not another. A different approach to outcomes adjusted for severity of illness is being investigated for therapy of breast cancer, in which therapy is allocated only to the patients at highest risk, whose outcome is then compared with that projected from a less compromised population on standard therapy, according to a mathematical model. This technique and all of the regression models used to control for cohort differences would require a deeper knowledge of risk profiles and outcomes for advanced heart failure than that which currently exists.

## **Vital Role of Registries**

The absence of broad-based data and the magnitude of mortality, morbidity and resource utilization argue strongly for the creation of a registry of

advanced heart failure. Such a multi-center registry would advance both risk stratification for outcome prediction and the development of a multivariate regression model to help adjust for differences between cohorts. Greater confidence in our ability to identify high-risk populations would sharpen trial design and accelerate recognition of devices in the breakthrough realm. Design of RCTs would be streamlined by better selection of target populations and better prediction of event rates.

There is now broad consensus that responsible progress in the field of mechanical circulatory support requires the establishment and maintenance of a mandatory registry that includes all implantable devices, both before and after approval. It should be possible to require specific baseline data collection on patients with mechanical assist devices after device approval if that stipulation is formally linked to the initial approval. By contrast to pharmaceutical therapies, which are easier to study before approval and harder to track afterward, mechanical circulatory support devices may, with appropriate registry documentation, be supported by a weight of evidence distributed differently between pre- and post-approval experiences.

## **The Near Future**


The lessons learned through the use of current technology have led to formative strategies regarding the timing of implantation, rehabilitative potential and discharge management in patients supported with circulatory assist devices. However, limitations of systems requiring external power sources connected through percutaneous drivelines have led to the development of numerous systems that are as completely implanted in the body as possible. This has resulted in developments along two broad approaches. The first is a refinement of implantable pulsatile systems, including the Abiomed and Penn State/3M total artificial hearts, the Thoratec IVAD, the Novacor II, the World Heart Heartsaver VAD and the Arrow LionHeart VAD. The majority of

these systems utilize transcutaneous power transmission and either an integral or component volume compensatory mechanism. A second thrust utilizes a completely new concept of axial flow technology for chronic support and includes the Nimbus/TCI HeartMate II, Intracorporeal Ventricular Assist System (IVAS), the Jarvik 2000 IVAS and the DeBakey/Micromed IVAS. These systems also depend on transcutaneous power transmission but eliminate the need for volume compensation. The AB-180 Circulatory Support System, the HeartMate III LVAD and the CorAide are devices based on centrifugal principles. In many ways our limited understanding of the impact of this latter group of devices may dictate newer study design principles.

Although there are no specific


standards for the pre-clinical evaluation of newer mechanical circulatory support systems, guidelines do exist. A Preliminary Draft Guidance for Ventricular Assist Devices and Total Artificial Hearts issued by the FDA in December 1987 needs to be updated. The joint paper developed by the American Society for Artificial Organs (ASAIO) and the Society of Thoracic Surgeons (STS) addresses only reliability concerns for long-term devices and does not address emerging technology for which a comprehensive standard with criteria for pre-clinical testing is still needed. The revision of these guidelines becomes even more important as distinctions between short-, intermediate- and long-term support become increasingly blurred during clinical application. An interdisciplinary effort needs to address the devel-

opment of a comprehensive standard for the pre-clinical evaluation of blood pumps, taking into account the uniqueness of each system and its intended use, yet remaining sufficiently flexible to incorporate new clinical experience.



As the field moves ahead, it has become clear that no one trial design or set of standards will be ideal or appropriate for all of these devices, populations and stages of development. This document represents both consensus and controversy from leading scientists, clinical investigators, representatives of industry and regulatory agencies. One of the most important achievements of this conference may be the recognition that the pace of real progress in mechanical circulatory support will be accelerated by ongoing collaboration. 



# transplant 2001



[Goals and Objectives](#)
[Future Meeting Dates](#)
[Related Links](#)

Program Planning Committees and Meeting Staff  
General Info

General Info, Schedule and Registration  
**Schedule**

Abstracts

Exhibits

schedule of activities

registration fees

**Postgraduate Course**

Scientific Program

Schedule at a Glance

Fri, May 11	7:00 a.m. - 7:00 p.m.	Sun, May 13	8:00 a.m. - 5:30 p.m.
Sat, May 12	7:00 a.m. - 5:30 p.m.	Mon, May 14	8:00 a.m. - 5:30 p.m.
Sun, May 13	7:00 a.m. - 7:30 p.m.	Tues, May 15	8:00 a.m. - 5:30 p.m.
Mon, May 14	7:00 a.m. - 7:00 p.m.	Wed, May 16	8:00 a.m. - 12:30 p.m.
Tues, May 15	7:00 a.m. - 7:00 p.m.	<i>Note: Concurrent Sessions will be held in both the Sheraton and Hotel Intercontinental Chicago.</i>	
Wed, May 16	7:00 a.m. - 12:30 p.m.		

**Exhibit Hours**

Sun, May 13	5:30 p.m. - 7:30 p.m.	<b>Sunrise Symposia</b>	
Mon, May 14	11:30 a.m. - 2:30 p.m.	Sun, May 13	6:30 a.m. - 7:45 a.m.
	5:30 p.m. - 7:00 p.m.	Mon, May 14	6:30 a.m. - 7:45 a.m.
Tues, May 15	11:30 a.m. - 2:30 p.m.	Tues, May 15	6:30 a.m. - 7:45 a.m.
	5:30 p.m. - 7:00 p.m.	Wed, May 16	6:30 a.m. - 7:45 a.m.

**Postgraduate Course**

Fri, May 11	1:30 p.m. - 5:30 p.m.	<b>ASTS Business Meeting</b>	
Sat, May 12	8:00 a.m. - 12:00 p.m.	Mon, May 14	5:45 a.m. - 6:45 p.m.

**Postgraduate Course Registration Fees**

	Pre	On site
ASTS/AST Member	\$235	\$265
Nonmember	\$335	\$365
Trainee	\$135	\$145
Nurse/Lab Tech/Coordinator/Pharmacists	\$135	\$145

**Pre-Meeting Symposia**

Saturday, May 12

Extended Donors/Allocation Symposium:  
Report from the Cadaver Donor Conference  
1:00 p.m. - 3:00 p.m.

**Pediatrics Symposium:**  
Transplantation in Adolescents  
1:00 p.m. - 3:00 p.m.

**Nurses/Coordinators Program**  
1:00 p.m. - 5:30 p.m.

**Basic Science Symposium:**  
Genomics and Proteomics Overview  
3:30 p.m. - 5:30 p.m.

**Clinical Science Symposium:**  
Anti-Microbial Resistance in Transplant Infectious Diseases  
3:30 p.m. - 5:30 p.m.

Sun, May 13	12:30 p.m. - 1:30 p.m.	<b>ASTS Business Meeting</b>	
Mon, May 14	12:30 p.m. - 1:30 p.m.	Mon, May 14	5:45 a.m. - 6:45 p.m.
Tues, May 15	12:30 p.m. - 1:30 p.m.	<b>AST Business Meeting</b>	
		Tues, May 15	5:45 a.m. - 6:45 p.m.

**Parallel Luncheon Workshops**  
*Limited Attendance*

Sun, May 13	12:30 p.m. - 1:30 p.m.	<b>Parallel Luncheon Workshops</b>	
Mon, May 14	12:30 p.m. - 1:30 p.m.	<i>Limited Attendance</i>	
Tues, May 15	12:30 p.m. - 1:30 p.m.	Sun, May 13	12:30 p.m. - 1:30 p.m.

*Note: Luncheon workshops will be located in both the Sheraton and the Hotel Intercontinental Chicago.*

**Poster Sessions (Presenters in Attendance)**

Sun, May 13	5:30 p.m. - 7:30 p.m.	Sun, May 13	12:30 p.m. - 1:30 p.m.
	with wine and cheese reception	Mon, May 14	12:30 p.m. - 1:30 p.m.
Mon, May 14	5:30 p.m. - 7:30 p.m.	Tues, May 15	12:30 p.m. - 1:30 p.m.
	with wine and cheese reception		
Tues, May 15	5:30 p.m. - 7:30 p.m.	<b>Registration Fees</b>	
	with wine and cheese reception		

	Pre	On site
ASTS & AST Members	\$275	\$295
Nonmembers	\$495	\$520
Trainees	\$175	\$205
Nurses/Lab Techs/Coordinators/Pharmacists	\$175	\$205

**Parallel Luncheon Workshop Registration Fees**

Members	\$30/luncheon
Nonmembers	\$45/luncheon
Trainees/Nurses/Lab Techs	\$20/luncheon

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# ASTS First Winter Symposium

## *Living Donor Adult-to-Adult Transplantation of the Kidney and Liver*

**T**he ASTS conducted its first Winter Symposium in Ponte Vedra Beach, Florida over the weekend of February 23rd - 25th. Attendance reached the maximum capacity of the facility with 141 attendees from the US, Europe, Japan, and Australia. The colloquium addressed the evolving art, science, and ethics of Living Donor, Adult-to-Adult Transplantation of the Kidney and Liver.

Ken Drazan, who is the Chairman of the ASTS Vanguard Committee, reported that with the assistance of the newly formed Vanguard Committee, junior members of the society were polled to study their practice habits, interests, and professional aspirations. We learned through this exercise that advanced surgical topics were an area of unmet educational training by the society. A secondary objective was to create new opportunities for recent and established members to build upon established and create new professional relationships. Toward this end, a meeting was devised to attract and rally an audience around a common theme of transplant surgery. A consensus was reached from a secondary poll that live donor surgery was an important topic of intense interest amongst the society in general. Given the enthusiasm and technology associated with live donor transplantation, a unique opportunity arose to weave these objectives into provocative symposium.

Darla Granger (Louisville) and Joseph Leventhal (Northwestern) organized and conducted the first day of the symposium focusing on renal transplantation. Initial presentations

described current technical approaches to kidney procurement from the adult living donor. Maria Millan (Stanford) began this discussion with a report of her center's experience using the minimal open-incision technique. Joseph Leventhal followed with a detailed description of instrumentation, positioning, and technical challenges to vascular anomalies. Stewart Wolf (Michigan) characterized the advantages and challenges of the hand-assisted nephrectomy, illustrating the facility gained by surgical trainees with added sensation. Eugene Cho (Maryland) reviewed the large experience derived from his center and

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illustrated the efficiencies garnered from high volume training of surgical fellows. Ken Chavin (MUSC) reviewed the radiological assessment of the adult donor, highlighting the value of computed tomography versus magnetic resonance imaging of the renal vasculature. The physiological and metabolic implications to the donor organ were discussed by Richard Perez (UC Davis). Paul Kuo (Duke) illustrated his approach to the complex donor with high body mass and challenging vasculature. The day concluded with Steve Bartlett (Maryland) and Arthur Matas (Minnesota) providing commentary on the importance of not just the donor surgeon's endoscopic expertise, but the recipient surgeon's abilities to reconstruct sub-optimal vasculature. Both panelists encouraged the use of carefully designed clinical studies to assess short and long term effects on the living donor and recipient.

Doug Farmer (UCLA) and Sandy Feng (UCSF) designed, coordinated, and conducted the liver forum on Sunday. To begin the discussion, Amadeo Marcos (Rochester) presented the indications for and standard evaluation of the adult donor and recipient. The radiologic evaluation of live hepatic donors was reviewed by Ann Fulcher (MCV) with particular attention to assessing hepatic steatosis. Elizabeth Pomfret (Lahey) and Michael Wachs (Colorado) provided outstanding technical videos of their respective institutions approach to right lobe donor hepatectomy and implantation techniques. Milan Kinkhabwalla (Cornell/Columbia) joined these faculty in a panel discussion to review operative challenges and strategies in the setting of complex and unexpected malformations. Kim Olthoff (Penn) reviewed an informal database of technical complications assembled with the assistance of John Renz (UCSF). To conclude, Nancy Ascher (UCSF), Ronald Busuttil (UCLA), Igal Kam (Colorado), and Charlie Miller (Mt Sinai) joined a panel discussion.

Important contributions to the program and organization of the meeting were graciously provided by Gail Durant, Jim Schulak, MD, and Tom Peters, MD. 🌐

## Consensus Conference on Maximizing Organs from Cadaver Donors

A conference on the most efficient utilization of organs recovered from the cadaver donor was conducted at the Crystal City Hyatt Regency in Arlington, VA on March 28–29, 2001. The conference was sponsored by the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST).

With an increasing number of marginal organ donors and a decreasing potential of available cadaver donors now evident, the best use of organs recovered from such donors needs a current and comprehensive analysis.

There were five work groups; heart, lung, liver, kidney and marginal donors. The format of the meeting was for each work group to address proposed questions on day 1, preparing a plenary presentation of the work group's deliberations on day 2 of the conference.

Leadership of the transplant community, including UNOS, representatives of AOPO, HHS, and the new Scientific Registry were invited and approximately 100 individuals participated.

The contributions of this conference are anticipated to have an impact upon current practice and a paper will be published.

The meeting was co-chaired by Francis Delmonico and Bruce Rosengard. Work group co-chairs were: Liver: Ronald Busuttil and Jean Emond; Kidney: John Roberts and Ed Alfrey; Lung: Ed Garrity and Robert Love; Marginal Donors: Mitchell Henry and Sandy Feng; Heart: Bruce Rosengard and Jon Zaroff. 🌐

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University of Cincinnati

Sherfield Dawson, III, MD  
Medical College of Virginia

Fong-Liang Fan, MD, FACS  
Saint Francis Medical Center

Peter D. Furness, III, MD  
The Children's Hospital

Maria Koulmanda, PhD  
Massachusetts General Hospital

Aloke K. Mandal, MD, PhD  
Hennepin County Medical Center

Robert A. Montgomery, MD, PhD  
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Rhode Island Hospital

Marty T. Sellers, MD  
University of Alabama-Birmingham

You Min Wu, MD  
University of Iowa Hospitals & Clinics

Yong-ran Zhu, MD, MS  
Medical College of Wisconsin

### MAY 2001

May 5 - May 11  
**AMERICAN ACADEMY OF NEUROLOGY  
ANNUAL MEETING**  
Philadelphia, Pennsylvania  
Contact: 651-695-1940  
Website: [www.aan.com](http://www.aan.com)

May 12 - May 16  
**TRANSPLANT 2001 JOINT MEETING OF THE ASTS  
AND THE AST**  
Chicago, Illinois  
Contact: 856-439-0880

### JUNE 2001

June 2 - June 7  
**AMERICAN SOCIETY OF COLON & RECTAL  
SURGEONS ANNUAL SCIENTIFIC MEETING**  
San Diego, California  
Contact: 847-290-9184  
Website: [www.fascrs.org](http://www.fascrs.org)

June 20 - June 22  
**APOO ANNUAL MEETING**  
Minneapolis, Minnesota  
Website: [www.aopo.org](http://www.aopo.org)

### JULY 2001

July 11 - July 13  
**INTERNATIONAL LIVER TRANSPLANTATION SOCIETY  
JOINT MEETING WITH ELTA AND LICAGE**  
Berlin, Germany  
Contact phone 49-30/450-529 60 or email [ilts2001@charite.de](mailto:ilts2001@charite.de)  
Web site: [www.ilts-berlin.de](http://www.ilts-berlin.de)

### OCTOBER 2001

October 24 - October 27  
**TRANSPLANT IMMUNOSUPPRESSION 2001:**  
The Complete Care of the Transplant Patient  
Minneapolis, Minnesota  
Contact email: [cmereg@tc.umn.edu](mailto:cmereg@tc.umn.edu)

### DECEMBER 2001

December 6-8, 2001  
**Professional Postgraduate Services/Thomson Healthcare  
2ND INTERNATIONAL CONGRESS ON IMMUNOSUPPRESSION**  
San Diego, California  
Contact Fax: 888-780-0663  
Website: [www.ppscme.org](http://www.ppscme.org)

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