# MARCH 2013, VOLUME 4, ISSUE 11
FOCUSING ON MECHANICAL CIRCULATORY SUPPORT

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With only a couple of months left in my tenure as MCS Council Chair, I suppose it is a good time to reflect on the past year. We certainly have been busy over the past 10 months or so, with the final edits, reviews and subsequent submission and publication of the ISHLT MCS Guidelines. Their publication is culmination of literally years of work, organization by more contributors and reviewers than I have room to thank. However, we certainly do not look at these guidelines as the final word by any means, given the growth and the pace of discovery, and it is our anticipation that these guidelines will need to be updated in the next several years.

This year’s annual meeting in Montréal has another strong MCS program, thanks to our Program Committee representatives Joseph Stehlik and Soon Park as well as all of the members who contributed many excellent suggestions for symposia. The MCS Council also organized a reprise of the ISHLT MCS Academy for the Tuesday prior to the start of the meeting. This year the Academy is also accompanied by a detailed Core Curriculum developed under the leadership of Salpy Pamboukian, the MCS Council’s Education Committee representative. The 2012 Academy was well received and we hope to improve upon our efforts, particularly with a focus on increasing faculty/participant interaction, due largely in part to the many excellent suggestions from last year’s attendees. There are still a few spots left for those who have an interest in registering. The full Academy schedule and speakers can be found on the MCS Council website.

Speaking of the annual meeting, please try to make plans to attend the MCS Reimbursement Session from 5:30-7:30 in room 512H. This session will feature both US and international perspectives on reimbursement from industry as well as physicians and is open to all members of the ISHLT. We have also asked Frank Irwin from OptumHealth to present the perspective of the payers. His presentations are always provocative as well as informative, so make sure to put it on your conference schedule.

I would also like to thank Evgenij Potapov, the MCS Council Communications Liaison for leading the efforts to put together content for this month’s ISHLT Links, as well as contributions throughout the year. The MCS Council wrote a summary of the Prague meeting as well as the American Society of Transplantation’s annual meeting. An excellent MCS year in review was written by Arie Blitz and Evgenij Potapov and covered a multitude of topics including new devices, surgical issues, cost effectiveness and thoughts about the future of MCS.
Other Council activities have included presenting on behalf of the ISHLT at this year’s MEDCAC meeting in addition to representatives from the ACC, AHA, INTERMACS, STS, and the Heart Failure Society. We are also partnering with the Pulmonary Hypertension Council’s upcoming pulmonary hypertension in left heart disease initiative. In the wings we are in the planning stages of an online MCS topic review which will hopefully provide a web-based resource for pertinent literature that will be available to the ISHLT membership. Keep an eye out for upcoming announcements on the progress of this effort and for opportunities to become involved.

Lastly we will be notifying the membership of positions opening up within the MCS Council for whom we will be accepting nominations. Danny Goldstein from Montefiore Medical Center in New York, our current Vice Chair, will be taking over as Chair of the Council upon the completion of this year’s annual meeting in April. The Council will be in extremely capable hands under Danny’s leadership and I look forward to another very productive year. With this change the position of co-chair will be open and we are currently accepting nominations. Please feel free to nominate yourself or someone else via email to me (teutebergji@upmc.edu) and copy Susie Newton (susie.newton@ishlt.org). A more formal announcement of the positions, their duration, and responsibilities will be circulated in the near future. We hope to have the final set of candidates completed prior to the annual meeting so that voting can take place during the MCS Council meeting on Friday, April 26, from 12:10-12:55 PM in Room 513ABC of the Palais des congrès de Montréal.

Disclosure statement: The author discloses receiving consulting fees from Sunshine Heart, and is on the Advisory Board for XDx.

Dr. Teuteberg is an assistant Professor of Medicine, Associate Director of the Cardiac Transplant Program, and a member of the Heart Failure/Cardiac Transplant section of the McGowan Institute for Regenerative Medicine at the University of Pittsburgh and UPMC, Pittsburgh, Pennsylvania, USA.
There is no doubt that mechanical circulatory support, especially by left ventricular assist devices, prolongs life and improves its quality.

Since last year, two competitive LVADs have been commercially available in the USA and Canada. In Europe and other countries across the globe, several other LVADs are approved for clinical use, but these two LVADs – the HeartMate II (Thoratec) and HeartWare HVAD (HeartWare Inc.) - are those implanted in more than three quarters of patients receiving mechanical support worldwide.

This situation offers the unique opportunity to compare the two pumps in a clinical setting. In the recently published JHLT editorial, centrifugal and axial flow pumps are analyzed in terms of their impact on hemodynamics, hemolysis, and dependency on preload and afterload, based on theoretical data and in vitro experiments [1]. Few clinical studies are available and those existing are mostly of an observational nature; the number of patients studied is too small to draw any meaningful conclusions. An analysis performed at our institution of the long-term follow up of more than 300 patients showed different complication profiles of HeartMate II and the HeartWare HVAD. While patients on HeartMate II pumps tended to suffer from cable damage in the long term [2], those supported with HeartWare more often had pump thrombosis [3], but the overall outcome seemed to be much the same. These studies also showed that, after weak points had been recognized and the pump design was changed, the incidence of complications for both pumps dramatically decreased.

The main question that arises is the scientific and ethical value of a prospective randomized study involving both pumps. A typical example of a prospective randomized study is the Formula 1 motor race. Of course, the driver’s skills do contribute to the success of the team but it is also a (scientific) fact that, after Michael Schumacher switched from Ferrari to the Mercedes team, he did not win a single Formula 1 race. On the other hand, cars from the same team mostly rank close to each other, showing that the technology is more important than the driver’s skills or mental state – in our case the surgeon’s expertise or the hospital as the care provider. On the other hand, we buy our cars based on many decision criteria, but the winner of the 24 hour Le Mans race or of the Paris-Dakar rally is known and this knowledge influences our decision. Of course such simplified examples do not consider many details, but the question we are facing is: “Are we ready for the race? Are we ready for prospective direct comparison of LVADs available on the market?”

A prospective study should be designed to evaluate not only the complication profile of the available pumps but also other factors such as the satisfaction of the patient with the external components and of the surgeon with the internal.
In my personal opinion, in the short-term the study would help to eliminate the tossed coin as a decision-supporting tool in the surgical armamentarium and to find the optimal pump for the individual patient. In the long term, such a study would lead to faster improvements in pump design and in the satisfaction and better outcome of our patients.

Disclosure statement: The author has no conflicts of interest to disclose.

_**Dr. Potapov is a Senior Surgeon and Co-chair of the VAD Program at the German Heart Institute, Berlin, Germany.**_

References:

The World of Mechanical Circulatory Support after the FDA Approval of HeartWare: Is Competition the Answer to All Our Questions?

MATTHIAS LOEBE, MD, PhD, FACC, FCCP
ERIK E SUAREZ, MD
ARVIND BHIMARAJ, MD, MPH, FACC
Methodist DeBakey Heart & Vascular Center
The Methodist Hospital, Houston, Texas, USA
mloeb@tmhs.org

Humans compete usually for food and mates, though when these needs are met deep rivalries often arise over the pursuit of wealth, prestige, and fame. Competition is also a major tenet in market economy and business is often associated with competition as most companies are in competition with at least one other firm over the same group of customers.
--WIKIPEDIA, Definition of competition

There are two kinds of people, those who do the work and those who take the credit. Try to be in the first group; there is less competition there.
--Indira Gandhi

Competition has been shown to be useful up to a certain point and no further, but cooperation, which is the thing we must strive for today, begins where competition leaves off.
--Franklin D. Roosevelt

Mechanical circulatory support to help the failing heart has been around since the early 1960s. First used as post-cardiotomy support bridging patients to myocardial recovery (1), it was used as early as 1968 as a bridge to transplant (2). At the time, physicians were generally proponents of either transplantation or mechanical support devices. Few remember the bitter arguments between advocates of heart transplantation and advocates of mechanical circulatory support in those days (3). When heart transplantation re-entered the clinical arena in the late 1980s and early 1990s, the concept of mechanical support as a bridge to heart transplantation was revived. Some significant success was obtained with the use of pulsatile left ventricular assist devices (LVADs) and the REMATCH trial rekindled interest in the use of LVADs for destination therapy (4). However, device-related complications were significant and the long-term benefits with 1st generation LVADs were very limited. Thus, LVAD support remained a niche indication.

The implementation of 2nd generation, continuous flow pumps as long-term support in end-stage heart failure led to a dramatic change in the scope of mechanical circulatory support. When the first continuous
flow pump for long-term support was implanted into a patient in Berlin in 1998, the doors were opened for an expansion of LVAD use (5). Since then, the numbers of patients supported by LVADs and the length of support duration have constantly increased. When the first continuous flow pump was tested in a randomized fashion against 1st generation LVADs, vast differences in performance and reliability were reported (6).

More recently, the first completed study of 3rd generation devices shows non-inferiority to 2nd generation devices (7). This clearly indicates that when 3rd generation devices become commercially available, one should not expect a game changing event similar to the explosion of LVAD use after implementation of 2nd generation devices. Still, as the devices we use today are far from perfect, one can hope and expect that having a new pump on the market will add some significant potential to our armamentarium. But realistically, what is the impact of such a new device becoming available?

**Clinical Outcomes**

If one looks at the performance parameters reported in the FDA trial, there is little if any difference between the 2nd and 3rd generation devices (7). However, the report does not indicate the incidence of adverse events in the control group, which is composed of Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) data derived from concomitant LVAD implants. We know that the patient demographics are similar and that the control patients, having lower INTERMACS classes, seem to be sicker. It has also been pointed out that the risk of pump stoppage and pump thrombosis was somewhat higher with the 3rd generation HeartWare HVAD (HeartWare International, Framingham, MA) than in comparable reports for HeartMate II (Thoratec, Pleasanton, CA). Whether this is due to pump design-specific issues is unclear. It would, however, corroborate observations that pump thrombosis was not infrequent in the Ventracor trial, another 3rd generation device that did not progress to FDA approval due to financial collapse of the company. In the Ventracor experience, cable breakage, stroke, and pump thrombosis were not infrequent. It seems that the 3rd generation centrifugal pumps need higher levels of anticoagulation and are not as forgiving when anticoagulation is interrupted as the high RPM, axial flow, 2nd generation pumps (8-12); although an increased incidence of pump stoppage has been recently observed in the HeartMate II population as well. Some centers report up to 15-20% pump malfunction rates (personal communication), though the origin of this problem remains unclear. One might suspect subtle changes in pump production or in the management of patients on LVAD support. Unfortunately, a scientific, head-to-head comparison of 2nd and 3rd generation devices is still lacking.

Given the sensitivity of the device/patient system as a whole, this illustrates that one must be cautious in attributing differences between patient populations, such as in the HeartWare trial, to basic design principles. It remains unclear whether centrifugal pump design or magnetic levitation substantially improves the outcomes in clinical application of mechanical circulatory support.
Some have pointed out an increased incidence of right heart failure with the newer pumps (8,13). Again, it appears very questionable whether this phenomenon is rooted in the device design. One can only speculate that the smaller 3rd generation device does not provide as much support as the 2nd generation LVAD, leading to higher end diastolic filling pressure and less afterload reduction for the right ventricle. A smaller outflow graft may be responsible for a somewhat higher sensitivity to afterload increases for pump performance. However, both statements are, at this point, pure speculations that are not supported by clinical studies or bench testing. On the contrary, many feel, for the various reasons described below, that the technical advantages of the HeartWare device implant procedure will make it a preferred device.

**Technical Considerations - Does size matter?**
The 3rd generation device is smaller and can be implanted inside the pericardium. The smaller device may be more suitable for smaller patients, and preliminary experiences with pediatric and adolescent patients supported with the HeartWare LVAD are available (14-16). In addition, the snap connection at the left ventricular apical ring is a clear advantage. The device may lend itself more to a minimally invasive, off-pump approach for implantation (17). Not requiring a pump pocket also sounds like a significant advantage for 3rd generation devices; however, there seems to be no palpable disadvantage to having a pump pocket in 2nd generation devices. The feared pocket infections, a common reason for morbidity and mortality in first generation devices, are basically unheard of in the use of HeartMate II LVADs (18). Furthermore, the time it takes to create the pocket is of no significance. But can the pocket lead to issues in the geometry of the inflow cannula over time? Some have suggested that this is the case and we tend to agree: an intra-pericardial position could be of advantage. However, even with the pump sitting inside the pericardium, some believe that with an apical position, changes in chest geometry over time may affect pump function. As a result, implantation on the inferior surface of the left ventricle has been recommended (19).

**Expanding the Realm beyond Approved Indications**
A clear advantage of the newer pump design is their ability to be used for bi-ventricular support. Quite substantial experience has been published from Europe in this regard (13,20-22). However, due to regulatory constraints, this configuration has only been used in exceptional cases in the US (23,24). Obviously, a device that allows bi-ventricular support after simple, easy implantation would be a true extension of the surgical armamentarium. One could leave the native heart in the chest, start with left-sided support, and add a right-sided device when needed. The European experience shows the benefits of such an approach. One may also desire the more user-friendly external setup so that patients do not have to deal with multiple controllers and batteries (25).

**Long-term Impacts**
Everyone will agree that the future of LVAD therapy lays in the destination therapy application. At this point, however, FDA approval restricts the 3rd generation pump to use as bridge to heart transplantation. Not much is known about the long-term reliability of 3rd generation pumps. While more than 10,000
patients have received 2nd generation LVADs and some have lived for more than 7 years, the reported European experience with the 3rd generation pumps for long-term use is sketchy at best.

**International Comparison**

In Europe, 3rd generation pumps are widely used and seem to have close to a 50% market share in implants (26). Although reliable numbers are not available, with 2,500 implants worldwide and less than 150 in the US, HeartWare HVADs must have been used in more than 2,000 patients in Europe. Today, several single center retrospective observational reports from Europe offer some insight into the experience there. However, in contrast to the INTERMACS database, which reflects all implants in the US, no such in depth report exists from Europe making it impossible to value their isolated experiences with 3rd generation devices (27-31).

**Game Changers in LVAD Therapy**

In our opinion, the true game changing development today is the broad collection of data on LVAD patients in the INTERMACS database. The objective and detailed information available from INTERMACS and the conclusions derived from these observations have already started to transform the field of LVAD support (31). In a very short period of time, we will be able to answer many of the open questions that single-center experiences could not address.

**Advantages of Free Market and Competition**

In the end, a question remains as to whether competition will have a significant impact on our field. Of course competition is beneficial, even if the two products now FDA-approved for use as bridge to heart transplantation seem to have few discriminating features. Having options has helped to bring down the cost of mechanical heart valves and many other products in medicine. In addition, competition may prevent the field of mechanical support from being dominated by one company. One may expect that the end of a factual monopoly will be a good thing, but even this is hard to predict. As long as mechanical circulatory support remains a niche indication with fewer than 4,000 implants per year, none of the manufacturers will be able to produce large numbers of pumps - the only way to lower the sales price. It is likely that LVAD therapy will exit this niche position, although it will take quite some time before there are large numbers of device implants (32,33).

In addition to the above mentioned INTERMACS experience, a multitude of observations on LVAD support using 2nd generation devices have been and will be published. A search of PubMed yields 72 publications on HeartWare; not surprisingly, HeartMate exceeds this number with 261 publications. Again, in our opinion, these observations about LVADs will help us to advance the field as an evidence-based therapy. The implementation of a new and different device may add some interesting aspects to this.

We think everybody will agree that Thoratec, as virtually the sole player in the US market, has been quite responsible in understanding and supporting the needs of this therapy outside of the immediate sales
function. Thoratec has supported education, outreach, and research in the application of mechanical support in the US more than any other manufacturer in the medical field. Increased competition may force them to reduce their role in paving the way for awareness and growth in the field of mechanical support for heart failure. Those obligations will then fall back under the responsibility of physicians and medical societies. Personally, we have no doubt that cooperative efforts like INTERMACS will have a much more profound impact on our field than the implementation of 3rd generation assist devices. Learning from our combined experience, improving patient selection, identification and management of complications of this therapy, and developing strategies to provide safe and effective continuing care for patients on devices will have enormous influence on the development of the field.

The next revolutionary step forward will be the advent of circulatory support devices that can be implanted and will continue to function long term without any procedure-related morbidity. Only then will family practitioners and general cardiologists embrace the concept of mechanical support and the hundreds of thousands of patients suffering from advanced heart failure will be deemed suitable candidates for device implantation.

**Conclusion**

Having a new kid on the block certainly expands the possibilities of mechanical circulatory support. Innovation is always good; stopping where we are can never be enough. However, as we have established LVAD therapy as a valuable option in end-stage heart disease supported by ample evidence and reproducible outcomes, technical innovation has to show positive advancements in solid clinical studies. The 3rd generation devices have some intriguing features that promise serious benefits. Having more choices as implanters is beneficial; being able to explore less invasive implant techniques is intriguing. Nevertheless, as LVADs are used more and more as long-term devices, additional solid data on the long-term reliability of 3rd generation LVADs is desired. The new kid on the block has to be measured by the rather high standards achieved in recent years in the field of mechanical support. The careful study of our combined experience in using LVADs with lessons derived in patient selection, management, surgery, and long-term care will continue to have a defining impact on how this type of care is delivered in the coming years. While competition amongst the industry may help, cooperation between the medical professionals using the technology will be crucial for the widespread acceptance of a very promising therapy.

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Dr. Loebe is Chief of the Division of Transplant and Assist Devices in the Department of Cardiovascular Surgery at Methodist DeBakey Heart & Vascular Center, and Director of Thoracic Transplantation at the J. C. Walter Jr. Transplant Center, The Methodist Hospital, Houston, Texas, USA.

Dr. Suarez is a Cardiovascular Surgeon with the Methodist DeBakey Heart & Vascular Center, Houston, Texas, USA.
Dr. Bhimaraj is a Cardiologist with the Methodist DeBakey Heart & Vascular Center, Houston, Texas, USA.

References:

After half a century of clinical development, mechanical circulatory support (MCS) devices are now in widespread use for the treatment of advanced heart failure. With the completion of the first five-year phase of INTERMACS, the boundaries of device therapy have been defined and extended, with improved long-term outcomes allowing interest to shift toward placement of MCS devices into “less sick” advanced heart failure patients. Integral to the original intent of INTERMACS was a comparison to ambulatory patients living with advanced heart failure who are not currently receiving MCS. Until now, the lack of information on outcomes with continued medical therapy has limited the ability to advance indications for MCS into the “less sick”.

Although the progressively better outcomes with continuous flow left ventricular assist devices (LVADs) documented in INTERMACS might be anticipated to attract ambulatory patients not yet dependent on inotropes, such patients currently comprise fewer than 20% of device recipients [1]. As mechanical support moves into the less sick patient profiles, decision making will be increasingly influenced by factors beyond survival alone. There is an urgent need for functional and quality of life data in patients limited with advanced heart failure both before the decision to proceed with MCS, and after therapy [2]. MedaMACS, the Medical Arm of Mechanically Assisted Circulatory Support, will address these needs.

On January 17-18, 2013 clinicians from 12 VAD/Transplant centers across the United States gathered in Washington, DC for the inaugural MedaMACS investigators meeting. MedaMACS will map the terrain of contemporary medical therapy for advanced heart failure, identify ambulatory patients for current MCS devices, define a broader context for the next generation of MCS trials and future devices, and design integrated endpoints that move beyond survival alone. MedaMACS will enroll systolic heart failure patients with INTERMACS Profiles 4-7 and at least one heart failure hospitalization in the prior year, who are neither inotrope-dependent nor listed for cardiac transplantation. MedaMACS will characterize those patients who are not currently receiving MCS for various reasons, including relative contra-indications, their own preferences, or their characterization as “less sick” either by perception or objective criteria.

MedaMACS is set to launch in March 2013 and will be housed with INTERMACS at the University of Alabama Birmingham. The protocol has been developed with guidance from the National Heart Lung and Blood Institute. Target enrollment will be 300 patients at 12 certified destination therapy VAD centers in the United States, followed by comprehensive two-year clinical follow-up with timed endpoints of death, transplant or MCS placement. Two separate baseline face-to-face assessments one month apart will define the early trajectory of illness. Adverse events on medical therapy, such as recurrent hospitalization or stroke, will be determined and compared to those experienced after VAD. Of equal weight will be longitudinal determination of functional
capacity, health related quality of life, frailty, and satisfaction with therapy. For many ambulatory patients with chronic heart failure, the magnitude and predictability of expected improvement in functional status with a VAD will likely influence their decision to proceed with MCS more than the margin of survival benefit [3].

The feasibility of the MedaMACS approach has already been validated in a successful screening pilot study, which enrolled 168 patients at 10 JCAHO-certified MCS programs across the United States in 2010-11 using similar entry criteria. The MedaMACS screening pilot collected baseline data from usual care practices and had limited telephone follow-up through 12 months. These preliminary screening pilot data produced several intriguing findings that have informed the discussion about MCS deployment in less sick INTERMACS profiles, while providing a taste of what will become available from MedaMACS.

Highlights from the MedaMACS screening pilot were reviewed at the investigators meeting in January. Screening pilot participants had an average age of 57 years, a mean EF of 18%, and a median of 2 HF hospitalizations in the previous 6 months. In all, 91% would be at low or intermediate risk for LVAD implant according to the HeartMate II risk score [4]. Although a subgroup chronic heart failure patients may have low estimated perioperative risk for LVAD implant, some may rightfully ask: who would want an LVAD for ambulatory heart failure? After presenting the risks and benefits of MCS therapy, 56% of patients surveyed said they would definitely or probably want LVAD therapy [5]. Enthusiasm for LVAD increased in patients with sicker INTERMACS profiles, as assigned by their treating physician, further validating these profiles as a marker of disease burden.

Jeffrey Teuteberg (University of Pittsburgh) presented preliminary outcomes from the MedaMACS screening pilot. A surprising one in three participants either died or underwent VAD/transplant within 6 months of enrollment [6]. Screening pilot participants carried a significant burden of disease, as evidenced both by the high event rate with a medical therapy strategy and their willingness to consider invasive surgical therapy. Quality of life was also markedly reduced in MedaMACS participants when measured by the EuroQOL instrument. Though the degree of anxiety and depression along with pain and suffering in the MedaMACS cohort was equivalent to INTERMACS subjects before VAD implant, patients selected for MCS were more limited in mobility and self-care [7].

There appears to be a clear and present opportunity to improve the lives of patients with moderately advanced heart failure using current MCS devices, though more work is needed to refine patient selection. Michelle Kittleson (Cedars-Sinai Heart Center) outlined that 49% of MedaMACS participants had been previously evaluated for transplant and/or VAD therapy [8]. The decision to proceed with evaluation for advanced therapies was not consistently delineated by standard clinical features. These screening pilot data highlight the urgent need for better characterization and triage of heart failure patients to find those most likely to benefit from MCS therapy. The latest results from the MedaMACS screening pilot will be presented at the International Society of Heart and Lung Transplant Annual Meeting and Scientific Sessions in Montreal in April 2013.
In the years to come, MedaMACS will provide important context for the next wave of device studies in moderately advanced heart failure. The NIH has sponsored the Randomized Evaluation of VAD Intervention before Intropes Therapy (REVIVE-IT) trial to study NYHA class III patients ineligible for transplant [9]. In addition, the industry sponsored ROADMAP trial will be a prospective, non-randomized observational study of ambulatory patients with NYHA III/IV symptoms not dependent on inotropes [10]. Together with REVIVE-IT and ROADMAP, the MedaMACS program will help refine selection for MCS from the ambulatory heart failure population within which the greatest benefit of mechanical support is anticipated. MedaMACS will also fulfill the urgent need for parallel functioning and quality of life data in advanced heart failure patients both before the decision to proceed with MCS and after therapy. The synergy between INTERMACS and MedaMACS will support the new era of shared decision-making in heart failure that will be pivotal in moving toward the 21st century goal of patient-centered care [11].

Disclosure statement: The author reports no relevant financial relationships to disclose.

Dr. Stewart is an Associate Physician at Brigham and Women’s Hospital and an Instructor at Harvard Medical School, Boston, Massachusetts, USA.

References:

The 2013 International Society of Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support: Observations and Future Directions

Salpy V. Pamboukian MD MSPH
MCS Council Education Committee Workforce Leader
svpam@hotmail.com

The field of mechanical circulatory support (MCS) has evolved rapidly over the last two decades in regards to both medical indications and technologic advances. Significant milestones have included the adoption of MCS as an alternative to heart transplantation, known as destination therapy, as well as the move away from devices based on pulsatile flow towards those based on the concept of continuous flow. Over this time frame, competing interests have included physicians and hospitals who want to grow or establish new MCS programs, commercial entities wanting to sell their products, and third party payers who want to limit their financial liability. In contrast to cardiac transplantation where donor availability ultimately limits the number of procedure performed, the availability of MCS devices themselves are theoretically limitless and therefore no barrier to the number of procedures that could be performed. In the milieu of world-wide economic constraints and need for “austerity,” the use of expensive technologies such as MCS are vulnerable to scrutiny from outside entities.

Just as the management of advanced heart failure has evolved to broaden the role of MCS, the scope of our Society has changed as well. Today, a significant portion of the Society’s scientific efforts are now focused on MCS. In many regards, the ISHLT has been the vanguard for developments in the field. Therefore, rather than having industry, payers or other societies determining best-practices, the time was long overdue for the members of our Society, with our unique multi-disciplinary and international perspective, to put to paper the current state of knowledge in MCS in the form of a guidelines document. The outcome of this effort culminated in the inaugural publication of the “2013 International Society of Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support”.

The guidelines are divided into five Task Forces, addressing the management of the patient from the time of evaluation through implantation and over the long-term until transplantation, explantation or death. Two striking observations were apparent during this process. First, despite over two decades of experience with mechanical circulatory support, there is a significant lack of randomized controlled data guiding our management decisions as manifested in the majority of recommendations being “level of evidence C”. This is indicative of the difficulty of performing such trials in patient populations that are relatively small and in whom great resources already have been invested. When a patient with MCS presents acutely with medical illness, such as a stroke, the clinician’s goal is to resolve the issue as promptly as possible to avoid patient morbidity and mortality. How willing would this clinician be to
enroll this patient in a trial randomly assigning one management strategy over another? Similar to heart transplantation, individual clinician’s management decisions have traditionally been influenced by experiential and anecdotal evidence with many published research studies being of a retrospective nature.

Despite the lack of controlled data, the second observation worth noting was this: there were far more commonalities in approaching patient management issues than differences. Almost surprisingly, there was relatively little controversy regarding specific recommendations made by these guidelines during the development process. Again, this speaks to the workings of our society. Despite our diversity, the intimacy of our society allows for presentation of research and exchange of ideas at a grassroots level amongst those at the frontlines of the field. As a result, consistencies in patient management strategies have developed through the amalgamation of research and expert consensus.

Tremendous opportunity exists for future research in the field, despite the challenges. It is the hope of the Society that not only will this document be the “go to” guide of the current knowledge base for those caring for patients, but will serve as an inspiration for future research initiatives.

Disclosure statement: The author has no conflicts of interest to disclose.

Dr. Pamboukian is an Associate Professor of Medicine at the University of Alabama School of Medicine in Birmingham, Alabama, USA.
Should LVAD Implantation Be the New Gold Standard for Terminal Heart Disease?

THOMAS KRABATSCH, MD, PhD
CHRISTOPH KNOSALLA, MD, PhD
EVGENIJ V POTAPOV, MD, PhD
ROLAND HETZER, MD, PhD
Deutsches Herzzentrum Berlin, Germany

Due to a significant improvement in survival rates after ventricular assist device (VAD) implantations during the last years, the number of LVAD systems implanted worldwide has increased considerably. The 6-month survival in bridge-to-transplant patients, for example, rose to 93% [1], whereas in 2008 a rate of 82% had been reported [2]. Several factors have contributed to this improvement in the results. The systems are easier to implant than their predecessors, they are more durable and relatively easy to exchange in an emergency and, in the case of HeartMate II, the postoperative anticoagulation can be less intensive.

Although heart transplantation (HTx) is still regarded as the gold standard in the surgical treatment of terminal heart failure, this solution has been ailing progressively in recent years. In Europe, and especially in Germany, the number of organs available for heart transplantation falls significantly short of the needs of the growing number of patients with end-stage heart disease.

It is not only that far too few donor hearts become available to be able to offer transplantation to even the patients with the most urgent indication, but also far more patients die on the waiting list for a heart transplantation than is generally assumed.

It is true that the long-term results after HTx, with a survival rate of almost 50% after 15 years and more than 20% after 20 years, are unbeaten up to now [3]. However, when assessing these figures, it is mostly overlooked that during the waiting time for a donor organ, which in Germany is over 1 year with normal urgency status and over 100 days even with highest urgency [4], approximately 20%-30% of the patients die [5, 6]. And in Europe, increasingly liberal donor criteria have led to a mortality rate of over 22% in the first year after HTx [7].

Therefore it seems to be time to give some thought to alternatives to our current practice.

Should we perhaps declare LVAD implantation to be the primary therapy for terminal heart failure? This treatment is always available and is suitable for about 90% of the patients so far considered candidates for transplantation (around 10% of the patients, in our experience, need biventricular assist device implantation for a variety of reasons).

If one adds the reported 1-year mortality rate for HTx of 22% to the mortality on the HTx waiting list of approximately 20%-30% in the first year and compares these figures with the current survival rates after LVAD implantation, there should be a survival benefit for the LVAD patients at least for the first 3 to 5 years.
Changing our treatment strategy as described above would tend to further improve the results after VAD implantation in comparison with today’s situation, since currently most patients are selected for VAD implantation when their condition makes it improbable that they will survive the time on the HTx waiting list.

Such a change in treatment strategy for Germany, as an example, would probably lead to twice as many VAD implantations being performed every year.

Subsequently the patients could live for as long as possible with the LVAD. Failures of the VAD pumps or pump thrombosis could be treated in the long-term course by surgical pump exchanges. If, after years of VAD treatment, complications such as recurrent cable or even systemic infection or secondary right-sided heart failure occur, heart transplantation could be regarded as a “bail-out” solution. The latter, however, would probably apply to only a small percentage of patients.

Our aim is to kick off the discussion on how studies could be planned and performed to elucidate whether such a change in our policy would be beneficial.

We feel that the situation in Europe, and especially in Germany, demands that the medical community seriously considers ways of alleviating the current problems.

Disclosure statements: The authors have no conflicts of interest to disclose.

References:

IN THE SPOTLIGHT:

**ISHLT 2013 in Montréal**

**COMMITTEE & COUNCIL MEETINGS AND WORKSHOPS**

There are many meetings taking place at the ISHLT Annual Meeting in addition to the Scientific Sessions. Some are scheduled for specific groups, while others (such as the Scientific Council meetings) are open to all member delegates. Below is a list of upcoming meetings to help you plan your trip to Montréal.

**Tuesday, April 23**
- ID Fungal Workshop, 8:00 AM – 4:00 PM, Room 515C
- **ISHLT Board of Directors**, 8:00 AM – 1:00 PM, Room 512D
- Lung Path AMR Workshop, 12:00 – 4:00 PM, Room 512H
- **Education Committee**, 2:00 – 4:00 PM, Room 514C
- Heart Transplant Listing Criteria Consensus Workshop, 2:00 – 6:00 PM, Room 512D
- **Thoracic Registry Executive Committee**, 3:30 – 5:00 PM, Room 514B
- **Standards & Guidelines Committee**, 4:00 – 6:00 PM, Room 514C
- **Registries & Databases Committee**, 5:00 – 6:00 PM, Room 514B
- IMACS User Group, 5:00 – 8:00 PM, Room 512H

**Wednesday, April 24**
- **Basic Science & Translational Research Council**, 12:15 – 1:05 PM, Room 512D
- Junior Faculty Mentor Luncheon, 12:15 – 2:15 PM, Room 514C
- DCD Registry meeting, 12:15 – 1:15 PM, Room 512H
- Transplant Registry, 1:15 – 2:15 PM, Room 512H
- **I2C2 Committee**, 1:15 – 2:15 PM, Room 512D

**Thursday, April 25**
- Junior Faculty & Trainee Council, 12:00 – 2:00 PM, Room 514C
- **JHLT Editorial Board** Luncheon, 12:00 – 2:00 PM, Room 519A

**DID YOU KNOW...?**

治理体系 number one cycling city in North America by Bicycling magazine, Montréal is the birthplace of BIXI, the public, self-service, bike-sharing system adopted by other cities such as Boston, Melbourne and London.

Visit [What to Do in Montreal](#)
DID YOU KNOW…?

Montréal is first in North America for the number of restaurants per capita, with nearly 65 restaurants per square kilometer. It’s a foodie’s paradise!

Visit Montreal Restaurants

DID YOU KNOW…?

Montréal’s ‘heart’ is Mount Royal, a stunning urban park and nature reserve designed by Frederick Law Olmstead, the creator of New York’s Central Park. Visit Mount Royal and Surroundings

Saturday, April 27

- Council & Committee Reports to the Board, 1:30 – 3:00 PM, Room 513DEF
- ISHLT Board of Directors, 3:00 – 9:00 PM, Room 514C

See you in MONTRÉAL!

Friday, April 26

- MCS Council, 12:10 – 12:55 PM, Room 513ABC
- PH Council, 12:10 – 12:55 PM, Room 513DEF
- PEDS Council, 12:10 – 12:55 PM, Room 514B
- NHSAH Council, 12:10 – 12:55 PM, Room 514C
- ID Council, 12:10 – 12:55 PM, Room 512D
- HFTM Council, 1:05 – 1:50 PM, Room 513ABC
- PULM TX Council, 1:05 – 1:50 PM, Room 513DEF
- Pediatric Heart Failure Workforce, 1:05 – 1:50 PM, Room 514B
- PATH Council, 1:05 – 1:50 PM, Room 514C
- PHARM Council, 1:05 – 1:50 PM, Room 512D
- Pediatric Lung Transplant Workforce, 1:05 – 1:50 PM, Room 512H
- Past Presidents Reception/Meeting, 5:30 – 7:00 PM, Room 519A

- Pulmonary Tx QOL Workforce, 12:00 – 2:00 PM, Room 512H
- 2014 Annual Meeting Program Committee, 12:30 – 2:00 PM, Room 514B
- PH in LHD Workshop, 4:30 – 6:30 PM, Room 512H

Thank you in MONTRÉAL!
A Journey to the Other Side: Part 1
Stewart Howard

I hadn’t planned on dying. That wasn’t part of my view of an enjoyable, early retirement. Instead, I formed a plan many years before the target date of 4th July, 2011 and being dead wasn’t included. I thought the date was a bit cute – Independence Day, fireworks and all that stuff for those on the other side of the Pacific. My personal Independence Day would result in no more committees, no more paperwork and no more budgets! In short, no more work.

As an engineer, I planned every detail. I believed that after decades of long hours, remote locations and sacrifice, I would opt out at the age of 56. Putting the plan into action involved debts being neutralised and savings converted to a diverse group of income-bearing assets. Then I had to get down to the important stuff. Boys’ toys were critical. A four-wheel-drive became a foundation piece. This was linked to the purchase of a camper-trailer allowing the bush to become a long-term holiday destination. Throw in a musical instrument for mental stimulation and boyhood dreams. Then there was the shed. Add a couple of Harley-Davidsons, a well-sorted workshop and retirement should overwhelm my best expectations. I had all bases covered!

Or so I thought.

I sat in the surgery office of my long-term GP. “I beg your pardon, could you repeat that?” said my doctor. His back was turned to me as he chatted on the phone to a specialist whom I had recently visited. “Jesus Christ! Are you serious?” he blurted into the phone.

My heart rate increased. As the outsider to half a conversation, I didn’t like the way this phone call was heading.

My GP put down the phone and turned to me. “Sorry about my outburst, Stewart. I wasn’t expecting such a report from your specialist.” Composing himself, the doctor said, “It’s not good news.”

Glassy-eyed, I looked at my GP, hoping that he would prescribe a couple of aspirin and a little rest. My heart rate must have topped 200 beats per minute. “Tell me how it is, Doctor.”

He looked down at the floor then back into my eyes. “You have terminal lung disease, Stewart. You will be dead before next Easter. That’s unless you are lucky enough to be given a lung transplant.”

Driving home from the surgery was a blur. Nothing seemed to fit. My mind rattled like a bagatelle, the small shining ball bouncing off every conceivable value that I held dear.
Back home, I sat on our elevated veranda together with my wife, Barbara. For once, I didn’t notice the view. As I conveyed my news, the look on Barbara’s face was something I never wish to see again; as though someone most trusted had just stabbed her in the heart. Together we were devastated. Our joint retirement had been destroyed. Our lives together were about to end.

I began to visibly decline on a monthly basis, such was the aggressive nature of the disease. As a consequence, I could see high levels of distress in the eyes of my loved ones and friends every time we met. The effect was particularly cruel to my wife; she watched helplessly as I headed towards my end days. As the person at the centre of these events, I was intensely aware of the sadness my illness was causing to those near and dear. This became my major focus, more so than the fact that I was dying. From a personal perspective, I had come to terms with my own passing but could not reconcile the distress I was causing my family and friends. It felt like I was letting them all down.

I was a non-smoker and never worked in the asbestos industry. The specialists stated that my disease—Idiopathic Pulmonary Fibrosis—had no known cause and, unfortunately, no known cure. My options were simple: die in a few months or have a transplant. I chose the latter.

This may have been stating the obvious; however, choosing to have a transplant does not necessarily lead to being given one, or even being put on the waiting list. The decision is not as simple as, for example, choosing to buy a new car. There are no showrooms filled with body parts of differing chemistry and specifications. Transplant organs are a very finite resource. Additionally, there is no point in giving such a valued item to an irresponsible person.

I was soon to learn that the specialists would leave nothing to chance. Over the next three months, I was poked, prodded, scanned and X-rayed together with having multiple samples taken. The specialists even checked out my mental capacity to cope with the concept of a transplant by employing a psychologist.

November arrived. I was losing my capacity to contribute physically to any task. My coughing increasingly became debilitating. I couldn’t even get out of bed without triggering a wracking cough lasting three to five minutes.

Then the news broke. I was formally advised that I had achieved my desired outcome: I had made the transplant list, awaiting a possible donor. The emotions this created were diverse. Yeah! I might have a second shot at life – maybe. But it also confirmed the facts clear to all in my social circle – but stubbornly denied by me – that I was obviously dying.
The month of December, leading up to Christmas, was the very worst time of my life. Family and friends knew that I would soon leave for Brisbane in order to be close to the Transplant Centre. They held Good-Luck parties. People hugged me and shook my hand, wishing me “all the best” and “speedy return”. But I knew the rate of my decline was accelerating. Things of which I had been capable previously became impossible as the calendar pages turned. The specialist team in Brisbane advised me that I was positioned in a decreasing window of opportunity within which I would be sufficiently strong to withstand the rigours of such major surgery. But that window was rapidly closing. If a suitable donor wasn’t found quickly, the proposed operation would be cancelled as it would kill me. Consequently, not only did I have to deal with an ill-defined timeframe, I was heading rapidly to a point where, once reached, hope was gone. (I had formally been advised that the “waiting period” ranged from 2 hours to 2 years.)

From my Engineering days, I knew that there were always hiccups to any major project – despite the most rigorous planning while using the best people. I viewed my proposed operation in similar light. The specialist team in Brisbane might have a reputation for a very high rate of success, but in my declining condition, I expected the worst. I shuddered at the thought of waiting in an unfamiliar city while experiencing an ongoing decline in my health – separated from those whom I loved.

And all through this, I kept up a cheerful façade in the lead up to Christmas.

The handshakes and hugs continued. Each was like being hacked by a rusting saw. I did not believe that I would see those lovely people again. Eventually this led me to decline well-intentioned parties and dinners – they were tearing me apart. I can best describe that experience as a long slow walk to the gallows.

My mind headed into seldom-visited corridors of memory. With incredible clarity it engaged a review of all special events that I had experienced throughout my life. Good times, adventures, parties, career, family and friends. The list went on. In quiet moments I sat and “watched” my life unfold, a bit like watching old family movies. In computer talk, I was reviewing my entire hard-drive.

Part 2 will be published in the April 2012 ISHLT Links Newsletter.

Disclosure statement: The author has no conflicts of interest to disclose.

Stewart Howard is a retired engineer who enjoys golfing with his dear wife, motorcycling where it doesn’t snow and wild music on his electric guitar.

Photo Credits:
Photos 1 and 2: The author 13 months pre-transplant, on vacation with wife Barbara in New Zealand
Photo 3: Prior to transplant during the author’s worst Christmas: advising his grandson (age 5) that grandpa was leaving in the hope of securing a lung transplant.
First Naïve, Later Delinquent: How Immune Maturation Benefits and Jeopardizes Transplantation

Simon Urschel, MD
2013 ISHLT Annual Meeting Program Committee Member
simonurschel@med.ualberta.ca

Children are different, a rarely disputed fact. However, medical research and science persistently under appreciate the hints on how to improve transplant outcomes hidden by nature within the developmental stages of the maturing immune system.

Heart-transplanted infants are immunologically forgiving and rarely cause concern about rejection or graft vasculopathy. This is well documented in the ISHLT registry data: children receiving heart transplantation below 1 year of age have the best long-term graft survival of all age groups, despite the high mortality immediately after transplant, which is mostly associated with severe pre-transplant illness with 10-15% coming off ECMO support and associated non-cardiac pathologies of children with congenital heart disease. The current 1 year conditional survival within 21.3 years is almost twice as long as documented in adults, and taking into account the improvements from era to era, the estimated survival projections for the current generation of newborns requiring transplant are amazing.

This is not where it ends: the lesser need for immune suppression is common clinical knowledge, though not as well documented in literature as the more frequent use of CNI as monotherapy. Equal clinical outcomes for infant recipients of ABO-incompatible organs were shown recently unanimously in multiple long-term studies from various centers [1]. In fact, on the immunological level there is some indication that the tolerance towards the persistently present non-self-blood group antigen may also modulate the immune response towards other donor antigens. Class II HLA antibodies develop significantly less frequently in infants after ABO incompatibility compared to same age recipients of ABO compatible organs [2], the opposite of what would be expected from the addition of another non-self-antigen. The secret of this paradox remains unsolved although there is emerging evidence that the lack of responsiveness to polysaccharides in infancy plays a key role.
The chronically underestimated B cell system shows much more functional deficit than his older brother, the T cell response. Memory B cells are vastly absent at birth and rarely reach adult proportions earlier than 5 years later. Subsequently, responses to polysaccharide vaccines such as pneumococcus are found to be vastly absent in the first 18 months of life; consequently, invasive infections from bacteria hiding within polysaccharide capsules are more frequent and severe in these young children than any time later in life. Further contributing factors may include high prevalence of regulatory B cells and changes in the repertoire of effector and regulatory T cells associated to thymectomy. Thymectomy? The simple reason why cardiac surgeons remove an organ that fills about 50% of the upper mediastinum is that it is in the field of sight for the repair of a congenital heart defect And while it sounds fairly radical (or careless?) to the average immunologist, and the impact on later development of allergies, autoimmunity, persistent CMV infection and accelerated immunosenescence remains to be clarified, thymectomy may indeed support the capability of the young child to accept a foreign organ better than anyone later in life.

The thymus, or better its final involution, may also be a major contributor to another peculiarity of the maturing human organism: the unacceptably high rate of graft loss during adolescence, which exceeds the average of younger children and older adults up to ten-fold [3]. Of course there are major non-immunological contributing factors in this age period when group-intoxication with legal and illegal substances becomes much more popular than regular intake of a calcineurin inhibitor at 8:00 AM. Nevertheless, our teenagers would clearly support the statement that it’s not all their fault. The thymus involutes in response to increasing plasma concentrations of sex hormones, which themselves share some immune modulatory effects of corticosteroids. Lymphocytes have specific receptors for sex hormones as well as growth factors. The impact of the female hormonal cycle and especially pregnancy on a variety of autoimmune disorders, as well as flares of chronic infections, is well recognized as is the reduced need for immune suppression in the pregnant transplanted woman. Therefore, it seems obvious that the changes associated with this turbulent and hormone-soaked period are not limited to behaviour, mental and cognitive alteration, growth and metamorphose of almost every other organ in the body, but do include changes in the immune system. In vitro and animal data are increasingly available; however, there is an imminent lack of clinical research exploring the impact of natural changes in our patients and possibly pointing the way to therapeutic interventions.

It is time to recognize and appreciate the advice that can be drawn from natural maturation of the immune system. Exploring and understanding the mechanisms will open the door for ways to transfer the benefits of the immature immune system of the infant to the older patient. The challenges of adolescence need to be better defined on an immunological level and taken into account for a personalized and adapted immunosuppressive regimen. The pediatric project within the Canadian National Transplant Research Project will take a first step in that direction; however, there is still a long, but likely very rewarding, way to go.

**Disclosure statement:** The author has no conflicts of interest to disclose.
Dr. Urschel is an Assistant Professor of Pediatrics and Immunology, a Consultant Pediatric Cardiologist, and a member of the West Research Group Cardiac Transplantation in the Departments of Pediatrics, Surgery, and Immunology at the University of Alberta, Edmonton, Alberta, Canada.

References:

The Editor’s Curse

ANDREAS ZUCKERMANN, MD
ISHLT I2C2 Committee Co-chair
andreas.zuckermann@meduniwien.ac.at

Our distinguished Editor of the Journal of Heart and Lung Transplantation (JHLT) has held several leadership positions in cardiac transplant and cardiologic departments across the USA. Starting in New Orleans at The Ochsner Clinic, he became famous in the transplant community due to his work on IVUS detection of graft vasculopathy. In 2005, he moved to Baltimore as head of the Department of Cardiology at the University of Maryland. His last move was in 2012, when he went to Boston to take the position of Head of Cardiology at Harvard’s Brigham and Women’s Hospital.

What a career he has achieved … pause … drum roll … until now! I bow my head and prostrate myself in honor of his knowledge, creativity and success! But nobody knows his other side (damn Vincent’s Sense about Double Trouble and dualities), his dark side: He is THE ultimate nemesis of many young tough men who try to achieve the ultimate goal of America’s #1 sport: win the Super Bowl in the National Football League. After reviewing all data, cooperating with top statisticians and working with specialists who reviewed the outcome data in a blinded way, we came to the horrifying conclusion of our analysis: Mandeep Mehra is associated with the downfall of a football city. He brings with him: The Editor’s Curse.

Evidence has been put together and will now be published the first time ever to bring forward the horrible truth (illustrated in Table 1 below).

Evidence #1: Horror on the Bayou
The first evidence of The Editor’s legacy on New Orleans can be found in Pub Med.1 There is no clear evidence that he took his curse to the Saints before 1992. This manifests in the 12-4 Record of the Saints in 1992. However his curse struck the first time in the post season, prohibiting the saints to get their first playoff victory. The next years were up and down. Although 2000 was the year of the first playoff victory, the Saints totally crashed during the hurricane Katrina disaster. However, this was also the year where the Editor left for Baltimore and immediately the curse was gone: Playoffs in the first year after the Editor left and, finally, the long awaited Super Bowl victory in 2009. They were singing “Fiyo on the Bayou.”

Evidence #2: Ravenstown Ravaged
The Editor left New Orleans in 2005 to join the University of Maryland in Baltimore. The Ravens were a successful team at that time: winners of the Super Bowl in 2000 with a respectable post-season record of 71.4%. After the Editor’s arrival, the team immediately went down to a 6-10 record and fought the coming years for their playoff appearances. Although playoffs would be reached 4 times during the Editor’s stay in Baltimore, the post-season record was a cumbersome 5-5 (50%). However the first full year without the curse, they immediately went on to claim victory in Super Bowl XLVII on February 3, 2013. This shows 2 Super Bowl wins without the Editor and zippo, nada, none with him, quoth the raven nevermore.
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<th>Saints</th>
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<th>Patriots</th>
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<tr>
<td>Pre-Editor</td>
<td>56-40 (58.3%)</td>
<td>68-44 (60.7%)</td>
<td>121-39 (75.6%)</td>
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<tr>
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<td>97-127 (43.3%)</td>
<td>68-44 (60.7%)</td>
<td>25-7 (78.1%)</td>
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<td>69-43 (61.6%)</td>
<td>10-6 (62.5%)</td>
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<tr>
<td><strong>Playoff record</strong></td>
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</tr>
<tr>
<td>Pre-Editor</td>
<td>5-2 (71.4%)</td>
<td>13-5 (72.2%)</td>
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<td>2-3 (40%)</td>
<td>5-5 (50%)</td>
<td>3-2 (60%)</td>
</tr>
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<td>Post-Editor</td>
<td>4-2 (66.7%)</td>
<td>3-0 (100%)</td>
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<tr>
<td><strong>Super Bowl Record</strong></td>
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<tr>
<td>Pre-Editor</td>
<td>1-0</td>
<td>3-1</td>
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<tr>
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<td>0-1</td>
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<tr>
<td>Post-Editor</td>
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**Total**

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<td>10-10 (50%)</td>
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<td>0-1 (0%)</td>
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</tbody>
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You need even more evidence? Still not convinced? Well, the story has not ended.

**Evidence #3: The end of a Dynasty:**

In 2012 our Editor moved again to another city ... this time Boston, home of the dynasty franchise of the 2000’s, the New England Patriots. No one needs to show the record of the Patriots but to pick a few: 3 Super Bowl wins, almost always playoff births, mostly as divisional champion. However everything changed in 2012. The Patriots felt the curse in Super Bowl 2012 against the Giants (do you really believe that a franchise QB-WR combo drops the most important pass that easily?). The Editor’s curse hit Brady and his men! And the 2013 playoff ended in a clear home loss against the eventual Super Bowl winning team, the Ravens, with similar drops by the same people.... Come on, these are clear signs of the Editor’s curse. From the arrival of the Editor in Boston, the Pats have not won a Super Bowl. I even would argue further: the next years will be the end of the Patriots dynasty. And the Patriots success story will end.

The results show a highly significant and auspicious increase of Super Bowl wins for cities when the Editor left or before he arrived compared to cities when the Editor worked there.

So what is the summary of our in depth analysis?

1) If you want to get great heart medicine in your town: hire the Editor

2) If you want to kill a football franchise: hire the Editor

Limitations of the analysis: of course there might be factors other than the Editor that put a curse on NFL franchises. It might be the JHLT itself, bad coaching, player injuries or just bad playmaking by NFL stars. However, this is rather unlikely after working out the details. Nevertheless, we will consider a future multivariate analysis,
including all former Editors, other journals (pre- vs. post-editorial changes) and football associated factors.

Until then we have to send a warning to Boston, to the New England Patriots, that rough times are approaching. In contrast to legal affairs we believe the curse exists until proven otherwise that it is reliable and undeniable open and shut case. The Doors have struck. As Jim Morrison would say … this is the end my only friend, the end …

Disclosure statements:

1. The author is a friend of Dr. Mandeep Mehra
2. The author is a diehard New Orleans Saints football fan since 1978 (strange for a European person!)

Dr. Zuckermann is an Associate Professor of Surgery and the Director of Cardiac Transplantation at the Medical University of Vienna in Vienna, Austria.

References:

It is with great regret that we inform members of the death of Prof. Donald Esmore on 13th February 2013 in Melbourne Australia following a long battle with multiple myeloma.

Don trained in Cardiothoracic Surgery at St Vincent’s Hospital in Sydney before undertaking a fellowship in Cambridge. Returning to Sydney, he was a key team member in St Vincent’s early success of their Heart and Heart-Lung Transplant program. Don was appointed to the Alfred Hospital in 1989 to head up a second national heart and lung transplant program. With astonishing determination, hard work and extra-ordinary surgical skill he created one of the world’s leading heart and lung transplant programs.

His achievements both nationally and international were many, particularly his development and clinical translation of artificial heart technology. These many achievements were recognised with him being made an Officer of the Order of Australia in 2001.

He will be greatly missed by his many friends in the international heart and lung transplant community.
ISHLT 2013 in Montreal: IMACS Registry Booth and Meeting

JAMES K KIRKLIN, MD
IMACS Registry Committee Chair
jkirklin@uab.edu

The International Society for Heart and Lung Transplantation Registry for Mechanically Assisted Circulatory Support (IMACS) is proud to present the web based data entry system in the Exhibit Hall at the Palais des congrès de Montréal, Québec, Canada. The IMACS staff is diligently carrying out plans to provide an innovative exhibit booth that will provide a live demonstration of the IMACS Registry.

**IMACS Registry Booth**

The following will be available at the IMACS Registry Booth, April 23-26, 2013:

- IMACS Registry Live Demonstration – Training staff for IMACS will be demonstrating the web based data entry system
- Protocol and User’s Guide – Hard copies will be available for review and distribution

In addition to the demonstration and literature distribution, knowledgeable IMACS staff will be available to answer any questions that participants may have in regards to IMACS.

**IMACS Registry Users’ Meeting**

On Tuesday, April 23, 2013 at the Montreal Convention Centre, IMACS will have a Users’ meeting for all participants interested in the IMACS Registry. This meeting will take place from 5:00-8:00pm and we strongly encourage your participation as we provide a current update on IMACS and live web based data entry tutorial. If you are interested in attending, please email the IMACS staff at IMACS@uab.edu.

**Enrollment in IMACS**

IMACS will provide continuous monthly updates regarding enrollment until the 2013 ISHLT Annual Meeting in April.

IMACS currently has forty-one hospitals and three collectives that have expressed interest in participating and submitting data to the registry. Eighteen of these hospitals have moved forward with the enrollment process by initiating regulatory requirements and one hospital is enrolled. IMACS has also received additional email inquiries from new sites that are on the verge of enrolling as well and strongly encourage the ISHLT community to continue to spread the word.
Requirements for enrollment can be found on the IMACS website under the Site Enrollment section - http://www.ishlt.org/registries/siteEnrollment.asp. First, if a hospital or collective is interested in registration and enrollment in IMACS, they should complete an IMACS Registry Institutional Enrollment Form and submit it via email to IMACS@uab.edu. Next, an IMACS staff member will contact the interested site to continue the enrollment process. In order to be enrolled in IMACS, the following items or forms will be requested:

1. IMACS Registry Institutional Enrollment Form
2. International Society for Heart and Lung Transplantation Registry for Mechanically Assisted Circulatory Support (IMACS) Memorandum of Agreement
3. Human Subjects Research certification (Ethics Board, Institutional Review Board, etc.)
4. Completed Training – At least one IMACS staff member at the institution must complete the IMACS training process. A live web-based data entry training session will be scheduled with the designated staff member at each institution. This training will be conducted in English.

Each item or form will need to be completed satisfactorily before a hospital or collective is officially enrolled in IMACS. Once a hospital is enrolled, they will be sent a user name and password is sent to begin entering data into the IMACS Registry.

Friendly IMACS staff members are available to answer all questions or inquiries regarding the registry. Please send an email to IMACS@uab.edu. We are looking forward to hearing from you and meeting you at the ISHLT Annual Meeting in Montréal, Québec, Canada!

Disclosure of Statement: The author has no conflicts of interest to disclose.

Dr. Kirklin is Professor and Director of the Division of Cardiothoracic Surgery at the University of Alabama, Birmingham, Alabama, USA.
'Bloodless' Lung Transplants Offer Hint at Surgery's Future (nytimes.com)

iPad users can solve public health outbreaks (cdc.gov)

'A new heart and lungs would be a second chance at life': Meet the transplant patients at Papworth Hospital (mirror.co.uk)

New CDC Vital Signs: Smoking among those with Mental Illness (cdc.gov)

The Australian cigarette packet that puts you off smoking (guardia.com.uk)

Lung transplant recipient's kindness honoured (news.ca.msn.com)

PM considers making cigarette packets display graphic images of disease (guardian.com.uk)

Lung-transplant recipient climbs high to help fight disease (suntimes.com)

Heart transplant recipient falls in love with donor's sister (foxnews.com)

Philly-based advocacy group supports those given Second Chance through heart transplants (philly.com)

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Anti-Imperialism, The Other Side, and Reality

Vincent G Valentine, MD
Editor-in-Chief, ISHLT Links Newsletter
vgvalent@utmb.edu

It was the last Christmas Eve of the 19th century when an article by Wilbur Chamberlin was published in the New York Sun about the apparent collection of indemnities for damages done by the Boxer uprising to oppose foreign imperialism and Christianity in China. Chamberlin had interviewed a well respected Congressionalist minister, the Reverend Will Scott Ament, Director of the American Board of Commissioners for Foreign Missions. Ament was on a mission providing for 700 native Christians in China. He informed Chamberlin that he had collected 300 taels (a form of Chinese currency) for each of the 300 murders during the Boxer Rebellion in an attempt to punish the foreign influences in China. Ament also declared to Chamberlin that his compensation was only moderate when compared with the Catholics who insisted on a head for a head in addition to the monetary recompense.

Well, you guessed it, our ever popular Mark Twain, who by the 20th century had reached international acclaim following his world lecture tour at this juncture, commented on Chamberlin's report. His international stature was a projection of American power, and America had started exporting its ideals to other cultures. Twain called himself an emissary to the world. But during his tour around the world while delivering his lectures of the 1890s to the colonies of the British Empire, Australia, New Zealand, India and South Africa, he was shocked by the atrocities and social injustices occurring to local indigenous populations as the British had taken over with their administrations of government, ideals and exports of materials. In 1900, when he got off the boat from his world tour he stated. “I am an Anti-Imperialist; I'm opposed to having the Eagle put its talons on any other Land.”

Although missionary ideas had occasionally appealed to him, they became less attractive to him than usual, especially after the business of bloodshed reported in foreign lands. Twain responded to the Chamberlin article he was shocked that Ament would use blood money for the “propagation of the Gospel” and to promote the “blessings of civilization” to brothers and sisters who “sit in darkness.” Twain summoned to missionaries, “come home and Christianize Christians in the States!”

Twain’s embittered sarcastic response provides us with this bit of “dark humor” probably unfairly attacking Ament. “By happy luck we get all these glad tidings on Christmas Eve—just the time to enable us to celebrate the day with proper gaiety and enthusiasm. Our spirits soar and we find we can even make jokes; taels I win, heads you lose.” His dark humor was fierce. His anti-imperialism stance was firmly established and obvious in nearly all his writings in the last decade of his life. But the roots of this attitude have been lightly sprinkled in the form of humor from his earliest writings beginning with The Innocents Abroad and increasingly more overt in Following the Equator or More Tramps Abroad. Take note of
his rise to fame and how it auspiciously coincides with America’s rise to an international power. Perhaps Twain’s writings rapidly became embedded in the subconscious and social conscience of Americans in the last half of the 19th century. This may have boosted the confidence of America into its success in the early part of the 20th century yet at the same time Twain may have set the stage or perpetuated the attitude of isolationism in the United States.

From The Innocents Abroad he gives us the ability to take on the Old World from an American perspective. In Huck Finn, he teases the aristocracy and tyranny by using the names, The King and The Duke, for the “sham” characters. In Connecticut Yankee, Hank Morgan imposes his ideas on an unwilling population leading to destruction. Hank’s intentions were to bring the “blessings of civilization” to a primitive people. This is almost identical on how the powers of Europe justify their colonization of Africa and Asia. In Following the Equator, Twain, although indirectly is becoming more obvious on how he describes the way America has treated slaves and Native Americans. These points are evident in Tom Sawyer – Injun Joe, and in Pudd’nhead Wilson. Especially take note of this passage from his travelogue (his final book), Following the Equator, in the section while traveling through Australia. He witnesses the way the aboriginal population has been treated to generalize about colonial powers.

In many countries we have chained the savage and starved him to death; and this we do not care for, because custom has inured us to it; yet a quick death by poison is loving-kindness to it. In many countries we have burned the savage at the stake; and this we do not care for, because custom has inured us to it; yet a quick death is loving-kindness to it. In more than one country we have hunted the savage and his little children and their mother with dogs and guns through the woods and swamps for an afternoon’s sport, and filled the region with happy laughter over their sprawling and stumbling flight, and their wild supplications for mercy; but this method we do not mind, because custom has inured us to it; yet a quick death by poison is loving-kindness to it. In many countries we have taken the savage’s land from him, and made him our slave, and lashed him every day, and broken his pride, and made death his only friend, and overworked him till he dropped in his tracks; and this we do not care for, because custom has inured us to it; yet a quick death by poison is loving-kindness to it.

His world tour penned in this travel diary helped open his eyes to the happenings around the world. Then in 1901, his sentiments on Anti-Imperialism roar from the essay on To the Person Sitting in Darkness. This is the most acerbic and caustic piece Twain has ever written. In fact, William Dean Howells, Twain’s long time friend and literary critic, stated that “this is a great piece, publish it, then go and hang yourself to save the people that you’re going to offend the trouble of hanging you.”
The Person Sitting in Darkness is the best depiction of Twain’s sentiments on Anti-Imperialism. No one can guard against his tongue. With his mordant and sarcastic wit along with his international prominence, he attacked different targets from Western Missionaries in China (Boxer Rebellion), England’s behavior in South Africa (Boer War), the way the Kaiser and the Czar have been acting eastern Asian then finally climaxing with an attack at President McKinley “the Master of the Game” and America’s presence in the Philippines. Many politicians were disgusted and outraged with Twain, probably because they saw the realism in his sarcastic charges against imperialistic powers. This essay suggests that the Western Powers are ruining the market of the “blessings of civilization.” The Third World – those sitting in darkness are beginning to suspect that they are being sold a false bill of goods. You go into these nations claiming that these nations will get hope liberty, prosperity and justice. But the third world may not be getting what they pay for. “We’re exporting civilization with the wrapper off.” Twain points out that McKinley has allowed American’s policy to be corrupted by foreign influences, but he tries to be the social critic carefully. Twain wants to keep the readers on his side as he pushes the envelope on being a critic. Fortunate for Twain, it is only he who can take on the sacred idols, the revered icons of various cultural movements. It is through his humor he topples them and erodes their authority. Take note of this tribute of our country’s most sacred icons.

And our flag -- another pride of ours, our chiefest! We have worshipped it so; and when we have seen it in far lands -- glimpsing it unexpectedly in that strange sky, waving its welcome and benediction to us -- we have caught our breath, and uncovered our heads, and couldn't speak, for a moment, for the thought of what it was to us and the great ideals it stood for…

…And as for a flag for the Philippine Province, it is easily managed. We can have a special one -- our States do it: we can have just our usual flag, with the white stripes painted black and the stars replaced by the skull and cross-bones.

As this dark essay comes to a close, To the Person Sitting in Darkness, the reader may realize for whom the essay is really intended. We believe Twain is talking about the primitive peoples of the third world when in actuality, it’s us, the American readers who are sitting in darkness who need to have our ideas redeemed if not by the blessings of civilization then by the blessings of the ideals we claim to stand for.

Other dark writings by Twain include The War Prayer which is considered the greatest Anti-War statement in literature. But this piece was unpublished until after his death. Twain was always mindful of public reaction, he considered that he needed family support so he withheld its publication, he did not want to be seen as a Puddn’head. And besides, “I have told the whole truth in that, and only dead men can tell the truth in this world.”

Twain wrote a lot on social injustice, more than he published. His most outspoken attacks on injustice remain unspoken. He wrote a piece on lynching only published posthumously, The United States of
Lyncherdom. “I shall have not half a friend left in the south.” His most outspoken attacks on injustice remain unspoken. He could not resist the fear of alienating his audience. The vulnerability of unpopularity was too much for Mark Twain.

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Dr. Valentine is a Professor of Pulmonary Medicine and Critical Care Medicine, Medical Director of the UTMB Texas Transplant Center, and Director of Lung Transplantation at the University of Texas Medical Branch in Galveston, Texas, USA.
Quotable Quotes

Quotable quotes on car racing, competition, research, guidelines, and discussion, with a little Mark Twain thrown in for good measure.

On Car Racing:

It is amazing how many drivers, even at the Formula One Level, think that the brakes are for slowing the car down. – Mario Andretti

What’s behind you doesn’t matter. – Enzo Ferrari

Auto racing began 5 minutes after the second car was built. – Henry Ford

On Competition:

The healthiest competition occurs when average people win by putting above average effort. - Colin Powell

There are two kinds of people, those who do the work and those who take the credit. Try to be in the first group; there is less competition there. - Indira Gandhi

Competition has been shown to be useful up to a certain point and no further, but cooperation, which is the thing we must strive for today, begins where competition leaves off. - Franklin D. Roosevelt

On Research:

Somewhere, something incredible is waiting to be known. - Dr. Carl Sagan

Medical science has proven time and again that when the resources are provided, great progress in the treatment, cure, and prevention of disease can occur. - Michael J. Fox

Medicine is the only profession that labors incessantly to destroy the reason for its existence. - James Bryce

On Guidelines:

Traffic signals in New York are just rough guidelines. - David Letterman

And then ultimately what I tell the kids is: coaches can give you information, they can give you guidelines, and they can put you in a position. But the only person who can truly make you better is you. - Brandi Chastain

On Discussion:

The aim of argument, or of discussion, should not be victory, but progress. - Joseph Joubert

Discussion is an exchange of knowledge; an argument an exchange of ignorance. - Robert Quillen

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Near Misses, Near Hits
CLOSE CALL LEARNING EXPERIENCES

Have you encountered a situation or experience—a "near miss" or "near hit"—that yielded lessons on how to better manage patient care in the clinical setting, or conduct research in the lab, or lecture/teach in a classroom, or just how to do your job better? Do you have an experience to share with the ISHLT Links Newsletter readers about an occasion that taught you something significant about ways to improve health care in patients with end stage heart and lung failure? If so, we want to hear about it.

We encourage you to submit a brief (+/- 500 words) summary of your Near Misses, Near Hits to us for possible publication. Each month, the Links Newsletter will publish a collection of similar experiences sent to us by our readers. Sharing with others the benefit of your experience and the lessons you learned can be an invaluable aid to other health care providers.

You can send your summary directly to Susie Newton at susie.newton@ishlt.org. Put "Near Misses, Near Hits Submission" in the subject line; add your name and phone number at the bottom of the email.

Your report will be considered for publication in the new Near Misses, Near Hits page, and may be edited for style and length. Anonymity is guaranteed if you wish. No one but our Editor and Managing Editor will be permitted to access the report. Your name and telephone number are requested only so that the managing editor can contact you if necessary.

While we cannot guarantee your submission will be published, we can guarantee that we will closely review and consider using it. All Near Misses, Near Hits submissions become the property of the ISHLT Links Newsletter and may be republished.
EDITORIAL STAFF

EDITOR-IN-CHIEF

Vincent G Valentine, MD
University of Texas Medical Branch
5.112 John Sealy Annex
Route 0561, 301 University Blvd
Galveston, Texas, 77555
vgvalent@utmb.edu

SENIOR ASSOCIATE EDITORS

John Dark, MB FRCS
Freeman Hospital
Cardiothoracic Center
Freeman Road, Room 115
Newcastle Upon Tyne, NE7 7DN
UNITED KINGDOM
john.dark@newcastle.ac.uk

Marilyn R Johnson, MD
University of Wisconsin
E5/582 CSC (5710)
600 Highland Ave
Madison, Wisconsin 53792
608.263.0080
mrj@medicine.wisc.edu

Roger W Evans, PhD
Transplant Professionals.com, LLC
Rochester, Minnesota, USA
evans.roger@charter.net

Lori J West, MD, DPhil
University of Alberta
6-002 Li Ka Shing Research Inst. East
Edmonton, AB T6G 2E1
CANADA
780.492.3200
ljwest@ualberta.ca

Allan R Glanville, MD, FRACP
Cardiopulmonary Transplant Unit
Xavier 4, Victoria St, Darlinghurst
Sydney, NSW, Australia 2010
61.2.8382.3257
aglanville@stvincents.com.au
ASSOCIATE EDITORS

Cardiology:

Emma Birks, FRCP, PhD
University of Louisville
201 Abraham Flexner Way
Suite 1001
Louisville, Kentucky 40202
502.587.4384
emma.birks@louisville.edu

Stavros G Drakos, MD
University of Utah School of Medicine
Salt Lake City, Utah, USA
801.209.1749
stavros.drakos@u2m2.utah.edu

Junior Faculty & Trainees:

Daniel F Dilling, MD
Loyola University Medical Center
2160 S First Ave
Building 54, Room 131A
Maywood, Illinois 60153
708.216.5402
ddillin@lumc.edu

Infectious Diseases:

Stanley I Martin, MD
Ohio State University Medical Center
Division of Infectious Diseases, N-1148
410 West 10th Ave.
Columbus, Ohio 43210
614.293.5666
stanley.martin@osumc.edu

Pediatrics:

Christian Benden, MD
University Hospital Zurich
Division of Pulmonary Medicine
Raemistrasse 100
Zurich, CH-8091
SWITZERLAND
christian.benden@yahoo.de

Pulmonary:

Tereza Martinu, MD
Duke University Medical Center
106 Research Dr. Bldg MSRB2
Room 2083, Box 103000
Durham, North Carolina 27710
919.484.9735
tereza.martinu@duke.edu

MANAGING EDITOR

Susie Newton
ISHLT Headquarters
14673 Midway Road, Suite 200
Addison, Texas, 75001
972.490.9495
susie.newton@ishlt.org
INTERNATIONAL CORRESPONDENTS BOARD

Spain:

Javier Carbone, MD, PhD
Gregorio Marañon Hosp Immunology
Dr Esquerdo 46
Madrid 28007, SPAIN
34.91.426.5180
carbone@teleline.es

Japan:

Takeshi Nakatani, MD, PhD
Nat’l Cerebral & Cardiovascular Ctr
Dept. of Transplantation
5-7-1 Fujishiro-dai, Suita
Osaka 565-8565, JAPAN
81.6.6833.5012
tnakatan@hsp.ncvc.go.jp

Italy:

Luciano Potena, MD, PhD
University of Bologna
Cardiovascular Department
Pad. 21, via Massarenti, 9
Bologna 40138, ITALY
390.51.636.4526
luciano.potena@unibo.it

Austria:

Andreas Zuckermann, MD
University of Vienna
Währinger Gurtel 18-20
Dept of Surgery; Div of Cardiothoracic
Vienna A-1090, AUSTRIA
43-1-40400-5643
andreas.zuckermann@meduniwien.ac.at
COUNCIL COMMUNICATIONS LIAISONS

BSTR Council
Howard J. Eisen, MD, FAHA, FACC, FACP
Drexel University College of Medicine and Hahnemann University Hospital
Philadelphia, PA, USA
215-762-5080
Howard.Eisen@DrexelMed.edu

HF & TX MED Council
David P. Nelson, MD
Integris Baptist Medical Center
Oklahoma City, Oklahoma, USA
405-949-3349
david.nelson@integrisok.com

ID Council
Michele Estabrook, MD
St. Louis Children’s Hospital
St. Louis, MO, USA
314-454-6050
estabrook_m@kids.wustl.edu

Macé Schuurmans, MD
University Hospital Zurich
Zurich, SWITZERLAND
044-255-11-11
mschuurmans@me.com

JFT Council
Christina Migliore, MD
Newark Beth Israel Medical Center
Newark, New Jersey, USA
973-926-4430
CMigliore@barnabashealth.org

MCS Council
Evgenij V. Potapov, MD
German Heart Institute
Berlin, GERMANY
49-30-4593-2065
potapov@dzhb.de

NHSAH Council
Emily Stimpson, RN, BSN, CCTC
Cedars Sinai Medical Center
Los Angeles, California, USA
310-498-3739
emily.stimpson@cshs.org

PATH Council
James B. Atkinson, III, MD, PhD
Vanderbilt University Medical Center
Nashville, Tennessee, USA
615-343-9576
james.atkinson@vanderbilt.edu

PDES Council
Kimberly L. Gandy, MD
University of Missouri
Kansas City, Missouri, USA
kgandy@mac.com

PHARM Council
Steven P. Ivulich, BPharm
Alfred Hospital
Melbourne, Victoria, AUSTRALIA
61-405-747-447
S.Ivulich@alfred.org.au

PH Council
Veronica Franco, MD
Ohio State University
Columbus, Ohio, USA
614-293-4967
veronica.franco@osumc.edu

PULM TX Council
Tereza Martinu, MD
Duke University Medical Center
Durham, North Carolina, USA
919-484-9735
tereza.martinu@duke.edu