Regulatory Realities in Lung Transplantation
Christopher Wigfield, MD, FRCS
Advocate Aurora Healthcare
Christ Medical Center

Abstract
Regulation is imperative in health care provision. A plethora of statutes, directives and mandates exist and influence the delivery of care and clinical program development. Essentially, these principles ensure governance and aim to optimize outcomes, particularly in transplantation services. Specific metrics are applied to monitor a given specialty. Such regulatory realities have become a considerable factor when establishing and maintaining lung transplant programs. Comprehensive and meaningful regulatory practice may, however, be difficult to achieve in particular areas of medicine. Lung transplantation poses multiple extraordinary clinical challenges for individual patients and their providers. Even established programs must balance ambition to service with the demands of governance when considering the high risks in this sub-speciality. This article summarizes the complex context of regulation and its apparent impact on clinical care and program management in lung transplantation.

Introduction
The health care sector in the United States is one of the most strictly regulated industries. Lung transplant programs are a notable example of regulation for this purpose and there are multiple agencies involved in monitoring and enforcing standards of care.

Patients presenting for lung transplantation have irreversible pulmonary disease. Medical therapy alone may not provide a better outlook in that setting. There are, of course, clinical risks associated with transplantation. Lung transplant programs on the other hand are assessed according to set performance criteria and patient outcome associated metrics. These indicators are available to the public and are updated periodically. Significant deviations from expected standards result in eventual investigation of programs where required.

The complexities of statistics aside, the fluctuations of patients with higher risks receiving transplants can significantly impact any given transplant cohort. When assessing “performance”, metrics, rather than the meaning of efforts, will judge a program for the patient.

It is essential to remember that each patient presents with a unique pattern of issues and no exact formulaic approach can adequately predict risk of one-year mortality in lung transplantation.

There are a number of contributory factors that provide impetus for the practice of lung transplantation to remain “conservative”. The wait list phase of lung transplant candidates is often associated with deterioration and deconditioning. This adversely affects the transplant recovery. The donor organ quality is more frequently a factor for non-acceptance of allografts (lungs) compared with other solid organs. To strike the balance between risks and benefits for each case is the first task.

(Please see Regulations continued on page 3)
President's Notes
Cheryl A. Keeler
Second Wind Lung Transplant Association, Inc.

The Board of Directors welcomes you to our newsletter. We want to bring you up-to-date on the activities of the Board during the months of July, August, September and October.

Board of Directors: In the next month, you will receive an election letter for Board Members and Officers. At the first Board Meeting on January 8, 2019, we will be holding elections to fill vacancies on the Board. My term as a Board Member expires on December 31, 2018, as well as Board Members Tom Archer and Garry Nichols. At this time, I do not know if Tom and Garry will continue as Board Members. However, at the end of the year I will be retiring from the Board. It has been an honor and privilege to serve the membership as a Board Member, Vice President and President of the Board. Due to health concerns, I need to step back and spend as much time as I can with my family and loved ones. If you are interested in becoming a Board Member, please contact Garry Nichols at Garnich44@aol.com to obtain the necessary paperwork to complete for the Election Committee. Please consider giving back to the transplant community.

Even though I won’t be on the Board, I will always remain a member of Second Wind. Recently, we notified you and the Internet Email Support Group of our need for volunteers to help with many of the duties currently performed by Board members. You do not need to join the Board, although if you are interested in becoming a Board Member, we would love to have you. Second Wind doesn’t have any employees. All of the duties to keep this organization moving forward will have to be performed by volunteers under the direction of a Board Member. Listed below are areas we need help with.

A. There are numerous publications that provide lung transplantation news. We need someone to monitor these websites periodically to identify information to be shared with the membership via this newsletter and/or the Email Support Group. We will provide you with the web site information and the name of a Board Member you can communicate with to provide the information.

B. If you have experience with grant writing, or know someone who does, we need someone to research and write grants to help fund AirWays and the Financial Assistance Program. The types of grants we are looking for can be from

(Please see President continued on page 5)
Regulatory Principles

The health care sector in the US is extremely regulated. Numerous legislative acts, laws and directives directly or indirectly affect the practice of medicine in general and various subspecialties specifically. Not all principles of regulation are directly applicable to transplantation and it is a complex matter. Essentially, four “layers” of regulatory governance may be described in this context. At a primary level, a fundamental set of federal laws and acts exists in order to regulate the health industry. The next layer consists of a relatively more recent series of information and electronic record related regulations. A third layer is a spectrum of laws, orders and directives that govern health care employment, therapeutic drugs and biological hazards. These all have widespread applicability in clinical care provision. Additionally, a distinct set of transplant rules and regulations are in place with strong emphasis on patient protection and program performance assessment. Multiple authorities in turn implement these measures.

Several Agencies at Work

The United Network for Organ Sharing (UNOS) operates as a non-profit organization with the federal mandate to manage the United States’ organ transplant system. Oversight for UNOS is via Organ Procurement & Transplantation Network (OPTN) and Health Resources and Services Administration (HRSA) with a specific contract in place with the federal government. The specific task set includes the following: managing the national waiting list for candidates and matching donor organs, maintaining a valid database by the Scientific Registry of Transplant Recipients (SRTR) to record all US transplant activity; develop policies for the transplant community to facilitate transplantation and process; monitoring organ matching process and organ allocation according to policies; providing assistance to patients and families; educational role for transplant professionals and the public.

The SRTR provides the public and transplant professionals with registry analyses, in an ongoing effort to monitor organ procurement process and individual transplant program outcomes. This agency operates under contract from the HRSA. Most of the data used for analysis at SRTR is collected by the OPTN from transplant hospitals, organ procurement organizations (OPO) and immunology laboratories. OPTN utilizes the information from SRTR to help design organ allocation policy.

The Centers for Medicare & Medicaid Services, CMS, is a section of the federal Department of Health and Human Services (HHS). It has wide ranging responsibilities and complex organizational structure. It incorporates multiple major health programs including: Medicare, Medicaid, the Children’s Health Insurance Program (CHIP), and the Health Insurance Marketplace. CMS is solely responsible for transplant program certification. This, in turn, guides most insurance companies and private payers regarding their potential lung transplant program recognition and eventual reimbursement for clinical services beyond the Medicare and Medicaid programs.

The Food and Drug Administration (FDA) regulates a vast spectrum of issues impacting health care. The FDA has the authority to enforce over 200 laws related to public health and consumer protection including food products, cosmetics, therapeutic drugs, vaccines, blood products and certain tissues for transplantation.

The Center for Disease Control (CDC) has limited surveillance and detection responsibility in transplantation related issues. As a public health authority, the CDC supports transplants quality with guidelines and monitoring in an effort to ensure optimal infectious disease outcomes for recipients. The CDC evaluates transplant safety in two categories: organ safety and tissue safety. Both require improvements and laboratory based testing to aid superior identification of presence and transmission of infectious agents during organ transplantation.

(Please see Regulations continued on page 5)
Loyola Medicine Testing System
that Evaluates Donor Lungs
Before Transplantation

by Jim Ritter
Media Relations, Loyola University Medical Center
jritter@lumc.edu

MAYWOOD, IL-
As many as 80 percent of lungs from organ donors are not used, either because they are not in good enough condition to transplant, or there are doubts about their quality and there is no way to verify their condition.

An investigational technology called ex vivo lung perfusion (EVLP) potentially could increase the organ supply by providing a more informed evaluation of lungs that otherwise would be deemed ineligible for transplant.

Loyola Medicine recently performed its first transplant using a lung that was assessed with the EVLP system.

"Everything feels fine," said the patient, Bob Falat, of Lockport, Illinois. "All of the doctors, nurses and staff genuinely care, and they all did everything they could to make sure my transplant worked. Loyola is a special type of hospital."

Mr. Falat's transplant was performed by Mamdouh Bakhos, MD, one of the nation's most experienced lung transplant surgeons, and Syed Ali, MD.

Mr. Falat's transplant was performed as part of a multi-center clinical trial sponsored by Lung Bioengineering Inc. In the trial, a donor's lungs that appear to need further evaluation are flown to Lung Bioengineering's lung assessment center in Silver Spring, Md. After spending three to six hours functioning on the EVLP machine, the lungs are tested and examined. If they are found suitable for transplant, the lungs are flown to a participating center.

Mr. Falat received the donor's right lung, while the left lung went to a patient at another center.

The clinical trial is comparing 66 lung transplant patients such as Mr. Falat who receive EVLP lungs with 66 patients who receive standard lungs that qualified for transplant without undergoing EVLP. Loyola is the only Illinois center participating in the study.

Most donor lungs are not suitable for transplant because the organs are compromised by trauma (such as car and motorcycle accidents); pre-existing lung diseases; medical treatments such as extended mechanical ventilation; pneumonia; or the dying process. Depending on the injury, donor lungs can become bruised, swollen or waterlogged.

"Because transplant physicians do not want to risk using lungs that won't work well, they tend to be very conservative in what donor lungs they will accept for transplant," said Daniel Dilling, MD, Loyola's medical director of lung transplantation. Ex vivo lung perfusion is performed after lungs are removed from the donor. (Ex vivo means outside the body). The lungs are inflated with a ventilator and the blood vessels are perfused with a solution of proteins and nutrients. The perfusion is done at normal body temperature in order to mimic normal physiological conditions. The condition of the lungs is monitored with tests such as X-rays, bronchoscopies and oxygen level analyses. The donor blood remaining in the lungs, including medications, is diluted and filtered away. Also removed are blood clots. Antibiotics and anti-inflammatory drugs are administered as a precaution.

During the EVLP process involving Mr. Falat's lung, Loyola's lung transplantation team remained in close communication with the EVLP center. After reviewing test results, they determined that the lung - which would not have been deemed usable based on normally available information - was suitable for transplant based on the additional evaluation provided by the EVLP process.

"The lung is working very well, and Mr. Falat's prognosis is excellent, thanks to the life-giving generosity of his donor," Dr. Dilling said.

For years prior to his transplant, Mr. Falat suffered from a progressive lung condition called chronic obstructive pulmonary disease (COPD). By the time of his transplant, he was breathing supplemental oxygen 24/7, and even minor exertions such as tying his shoes left him winded.

"Unless you have the disease, you can't understand what it does to your life," he said. "If you can't breathe, you can't do anything."

Before he got sick, Mr. Falat, 72, was quite active. And now that he has the chance to breathe more normally again, he hopes to resume activities such as golfing, doing household repairs and taking his grandchildren fishing.

"I am forever grateful to Loyola, Dr. Dilling and all the staff who took care of me," Mr. Falat said.

For 30 years, Loyola has operated the largest and most successful lung transplant program in Illinois. Loyola has performed more than 900 transplants - more than all other Illinois Centers combined. Loyola's multidisciplinary team regularly evaluates and successfully performs transplants in patients who have been turned down by other centers in Chicago and surrounding states. Despite taking on more challenging cases, Loyola consistently records outstanding outcomes.

The clinical trial Mr. Falat is participating in is titled: "Phase 2, Multicenter, Open-label Study to Measure the Safety of Extending Preservation and Assessment Time of Donor Lungs Using Normothermic Ex Vivo Lung Perfusion and Ventilation (EVLP) as Administered by the SPONSOR Using the Toronto EVLP System."
small foundations, which require minimal paperwork submissions to be considered. The Board would be the resource for information.

C. Second Wind has a Marketing / Fundraising / Advertising Committee. This Committee is chaired by Vice President Frank Shields. We’re sure there are many businesses out there whose products would be of interest to the membership. Help is needed finding those businesses and securing advertising in AirWays and on our web site. A member of the Committee would follow-up with any businesses you find that have an interest in advertising.

D. The Second Wind web site was redesigned in 2016. We need help reviewing each and every page on our web site to make certain it is functioning as it should be and that the information contained on the site is still accurate. The new site is written in Word Press. Board Member Jane Kurz would work with you to make any corrections needed.

E. Second Wind tries to stay up-to-date on information related to the 75 lung transplant centers across the country. We need volunteers willing to stay in contact with their lung transplant center to be sure we have the latest information such as address, telephone numbers to the lung transplant department, email addresses, the name of the Medical Director, and Social Workers. Most of us have established close working relationships with the staff at the center where we received our transplant. We’d like to take advantage of that relationship by having you keep us up-to-date on the center information.

So far, we have only had one response to the above request for volunteers. Anything you can do will make a critical difference in keeping Second Wind alive and well.

Financial Assistance Program:
During the months of July, August and September, we spent a total amount of $ 4,992.39. So far in 2018, we have received a total of nineteen (19) applications for financial assistance. These nineteen applications are from thirteen different transplant centers across the country. The grants paid during July through September period were from applications received in 2015, 2017, and 2018. Most of the payments made were for temporary lodging while at their transplant center and gasoline cards to help with the cost of transportation. We did have one request to make a monthly payment to Blue Cross/Blue Shield for health insurance. The applicant’s father had been helping his daughter by paying for her health insurance, but he had a bad financial month and needed Second Wind to help with one month’s payment.

You will see later in this newsletter that Second Wind
COPD: Culmination of a 15 Year Study Creates a ‘Looking Glass’ Into Genome of Most Important Pathogen and How to Fight It.

by Ellen Goldbaum

Decades of work on chronic obstructive pulmonary disease (COPD) at the University at Buffalo and the Veterans Affairs Western New York Healthcare System have yielded extraordinary information about the pathogen that does the most harm to patients. The results, published recently in Proceedings of the National Academy of Sciences, provide the first insights into how this pathogen lives and adapts to its host in real-time over months and even years.

“By helping us understand how this pathogen survives in a hostile environment in human airways, this research is helping us develop ways to eradicate the pathogen to improve the lives and health of people with COPD,” said senior author Timothy Murphy, MD, SUNY Distinguished Professor and senior associate dean for translational research in the Jacobs School of Medicine and Biomedical Sciences at UB. Human airways include the nose, nasal cavities, the mouth, larynx, trachea and bronchial passageways.

The pathogen, nontypeable Haemophilus influenzae (NTHi), is the source of much of the misery that COPD patients endure, Murphy said. It is an exceptionally formidable adversary, he added, because strains adapt to each host. Having taken samples from 192 Western New York patients with COPD, he said, meant that researchers then had 269 different strains of the pathogen to study.

Thriving in a hostile environment

“People with COPD carry this organism in their lower airways for months to years,” Murphy said. “And since it’s a pathogen that doesn’t belong there, it causes all kinds of problems.

“It’s a hostile environment: The little hairs called cilia are continuously trying to get it out of the airway; that’s what makes patients cough. The immune system is bombarding it with antibodies and macrophages that are trying to eat it up, and with antimicrobial peptides, small molecules that are looking to punch holes in the bacteria. All of these things make it a challenge for these bacteria to live in the human airways.”

And yet they do survive and even thrive. To find out why and how NTHi survives, and how it might be overcome, Murphy and his colleagues were awarded a National Institutes of Health grant in 2013. It was part of a continuous 28-year-long grant from the NIH to Murphy and his longtime collaborator, Sanjay Sethi, MD, professor, chief of pulmonary, critical care and sleep medicine at the Jacobs School, division chief of UBMD Internal Medicine, a staff physician at the VA Western New York Healthcare System, and a co-author on the paper.

“Studies of this pathogen up until now have been looking at strains grown in labs or stored in freezers,” said Murphy. “The power of our study is that we have 269 strains of the pathogen and we can see what it looked like when the patient first acquired the strain and how it changed its genes to survive in the unique environment of the human airways,” he said.

Those genetic changes are key, he said, to determining where the pathogen’s vulnerabilities lie and what the best strategy might be to eradicate it.

The ability to efficiently sequence the genome of the pathogen and analyze it was critical to the success of the research, Murphy added.

‘Looking glass’ into pathogen’s past and present

“Not only were we able to look at what the genes looked like when the patient acquired the pathogen, but we followed these patients every month,” he continued. “One bacterium lived in a patient for four years. The genomes are like a looking glass, revealing the pathogen’s secrets to us by showing us how it changed its genes through the years.

“What we found is that the Haemophilus influenzae turns genes on and off, it’s constantly changing which genes are activated based on the environment in the airway,” Murphy explained.

Since the lower airways are nutritionally deprived, for example, the research demonstrated that the pathogen will activate all of its mechanisms to try and scavenge nutrients like iron that it needs to survive, he said.

That information is critical to potentially developing a vaccine or a treatment. “Now that we’re beginning to understand how the bacterium is able to survive, we can use these molecules that come from the genes we found as drug targets to eradicate the bacterium from the airways.”

“The beauty of this approach is that a new drug can be targeted specifically to an antigen,” Murphy said, “allowing selective eradication of the pathogen without disturbing the normal flora.”

(Please see COPD continued on page 7)
(COPD continued from page 6)

Translational collaborators
Murphy emphasized that the work resulted from a true collaboration — not just between him, Sethi and his other UB colleagues, but also with his other co-authors. They include longtime research partners Melinda Pettigrew, PhD, professor of epidemiology at Yale University and an expert in the molecular epidemiology of respiratory tract infections, and Hervé Tettelin, PhD, associate professor of microbiology and immunology at the University of Maryland School of Medicine and an international authority on microbial genomics.

The majority of the laboratory work was performed at UB, with most of the genomic sequencing performed by the genomics core at UB’s New York State Center of Excellence in Bioinformatics and Life Sciences.

In addition to the NIH grant to Murphy, Pettigrew and Tettelin, the work was also funded, in part, by the Department of Veterans Affairs, Office of Research and Development, and by the Clinical and Translational Science Award to UB.

Both Sethi and Murphy noted the most important collaborators were the 192 patients who visited their COPD study clinic monthly and consistently provided samples to the researchers over the course of the 15-year study.

“We are first and foremost grateful to these patients, who received close medical attention while they were contributing to the study and without whom this study could not have been done,” Murphy said.

Additional co-authors are Christian Ahearn, a PhD candidate in the Department of Microbiology at UB; Mary Gallo, an MD-PhD candidate at UB. Both are performing their thesis research in Dr. Murphy’s laboratory. Other co-authors include Janneane F. Gent and Yong King of the Yale University School of Public Health and School of Medicine, respectively; and James B. Munro and Adonis D’Mello of the University of Maryland School of Medicine.

Addendum: The work described in this article has the potential to lead to multiple new drug targets and treatment approaches. Regarding a timeline, a realistic estimate for when a new therapy may be available: perhaps 5 years until initial testing in early clinical trials and 10 years until FDA approval and widespread availability. These are only best estimates.

MEMORIAL DONATIONS

In Memory of John Jordan
by the following individuals
Robert Smith.
Megan O’Boyle.
William Payzant.
Eric Holzer & Family.
David and Laura Wallace.
Julie Strawn.
Dr. William III and Dorothy Carter.
Moore & Van Allen, PLLC, Attorneys at law
Capt. Brice and Elizabeth Moseley
Clyde and Gail Merrell

WE REMEMBER

Jack Norton
Hometown: Zanesville, OH
Transplant: 02/14/2002
Center: Ohio State University Medical Center
Date of Death: 01/08/2018

Luann Rizzo
Hometown: Glendale, NY
Transplant: 12/10/2010
Center: Newark Beth Israel Med. Center
Date of Death: 03/19/2018

The following two We Remember names had a family membership.

John M. Jordan
Hometown: Charleston S.C.
Date of Birth: 6/6/1940
Transplant: 3/22/2010
Center: Duke University Medical Center
Date of Death: 10/29/18

Name: Mary Jenkins Jordan
Hometown: Charleston, South Carolina
Caregiver to John M. Jordan
Date of Birth: 05-05-1942
Date of Death: 11-05-2018

Mary met Johnny at a high school dance when they were 15 years old. This began a love story that lasted 61 years. On June 9, 1962 Mary and John were married. Mary graduated from MUSC College of Nursing in 1963. For those 61 years they were dedicated to each other, their faith and their family, daughter Julie (Doug) Ostrover and son John Miles Jordan III (Deanna), and their six grandchildren. All of the comments made by their friends and loved ones say that Mary and Johnny were inseparable. Comfort can be taken because they are now together again. Mary’s death was unexpected just one week after Johnny passed away and the same day as John’s funeral. Rest in peace in the loving arms of each other and our Lord.

At the going down of the sun and in the morning
We shall remember them!
Teresa Toro Story

My name is Teresa Toro. I am 58 years old and a Bilateral Lung Transplant recipient as of February 26, 2016.

I was born in Santiago, Chile in South America and at the age of 4, in 1964, my family and I moved to the United States. I was born with a metabolic genetic disease called Alpha-1 Antitrypsin Deficiency. This was unbeknownst to me and to my parents at this point in my life.

Needless to say, I have always been very athletic and very involved in modern and jazz dancing and cheerleading all through Junior High and High School. I was also picked as a professional NFL cheerleader for The Miami Dolphins in 1978.

For over 30 years, I worked as a Legal Assistant and a Spanish Interpreter for many prestigious Law Firms and Lawyers throughout Miami, Florida.

I started showing signs of Asthma when I was 18 years old. It was not until February of 2010 that I frequently started getting admitted to hospitals with exacerbations and respiratory distress. I was subsequently diagnosed with Pulmonary Emphysema and in 2014, during Thanksgiving and Christmas, I had three back-to-back exacerbations and was somewhat bedridden and confined to a wheelchair most of the time and I was forced to move in with my elderly parents. In 2015, I knew that it was time to start evaluations for a double lung transplant since my lung capacity was only 21%. This is when I was also diagnosed with Alpha-1 Antitrypsin Deficiency. The evaluations took almost a full year to complete since it was hard for me to find transportation to my appointments. However, I was finally placed on the National Waiting List for Lungs on January 13, 2016.

My "Gift of Life" call came shortly after, on February 25, 2016, and I was successfully transplanted on February 26, 2016 with two beautiful pink lungs. Which I now know they belonged to my Angel Donor, Tommy.

If not for my life-saving transplant, I would have only lived 2 more months. I still have my disease, which may eventually affect my liver; however, I live each day as if it were a gift.

I am now dedicated to helping others. I am an Ambassador for Life Alliance Organ Recovery Agency and I am also a Mentor for The Lung Transplant Foundation. The Lung Transplant Foundation recently asked me to submit a quote on what mentoring means to me and this is my submission: "Mentoring makes me feel good, and allowing me to pay it forward makes me feel even better. The feeling I get when I hear and actually feel the sign of relief and comfort from my Mentee is priceless."

EDITOR’S NOTE

Dear Second Wind Members,

As the editor of the AirWays, the Second Wind Lung Transplant Assoc. Inc. newsletter sent to its members and all Lung Transplant Centers in the US, I would especially like to ask you to notify me of your new address when you move OR if you will be temporarily away on vacation, for evaluation for a lung transplant, for when you receive a transplant or any reason that your newsletter cannot be delivered to your address on file and the USPS is NOT holding your mail for you.

I will hold your newsletters until you notify me to send them to you and at what address. I also request Lung Transplant Centers to please email me the correct address to send the AirWays as some come back as undeliverable often for a lack of a specific building number, room number or name.

Please notify me at neuberger1234@comcast.net. Thank you so very much, your cooperation is very much appreciated.

Damian Neuberger, Ph.D.
AirWays Newsletter Editor
Bilateral Lung Transplant 10/19/97
Loyola Univ. Med. Center
Kidney Transplant 10/19/11
Univ. Wisconsin Hospital & Clinics
## Transplant Anniversaries

### JULY 2018

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<td>7/16/2012</td>
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<td><strong>Cathy McGill</strong></td>
<td>7/13/1985</td>
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<td>Nancy O'Mara</td>
<td>7/26/2016</td>
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<td><strong>Anita Tracey</strong></td>
<td>7/3/2005</td>
<td>13 yrs</td>
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<td>Gail E. Weadon</td>
<td>7/17/2015</td>
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<td>Gwen Herron</td>
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<td>Beth Mitchell</td>
<td>8/9/2011</td>
<td>7 yrs</td>
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<td><strong>Michele O'Guinn</strong></td>
<td>8/26/2004</td>
<td>14 yrs</td>
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<td>Eugene Swisher</td>
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<td>Karen Hand</td>
<td>9/20/2016</td>
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<td>Jerry Russell</td>
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<td>Cheree Peirce</td>
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<td>Daniel Russell</td>
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<td>Jerry Gray</td>
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<tr>
<td>Alan Schwenck</td>
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There were numerous anniversaries from members whose information is marked as confidential, so therefore we cannot list anything about their membership in *AirWays*.

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### Hike for Lung Health

On Sunday, September 16, 2018, Second Wind participated as a Charity Partner with the Respiratory Health Association, in the annual Hike for Lung Health, held in Lincoln Park, Chicago, Illinois. This annual event is held to increase awareness of lung disease and to raise money for research, education, and for Second Wind’s Financial Assistance Program. You and your fellow Hikers raised a total of over $40,000. Second Wind was able to fund-raise $7,150.00 of which $5,132.40 went to the Financial Assistance Fund and the remaining went to the organizers of the Hike for Lung Health for lung health research, education and the expenses for putting on the Hike.

Respiratory Health Association and the Hike partner charities share a common goal to reduce the suffering caused by lung disease, the nation's third leading cause of death and disability. Funds raised by Hike for Lung Health support RHA's and each of the partner's collective missions.

A special “thank you” goes to Frank Shields, Second Wind's Vice President, for all of his hard work making this event meaningful for all of our members. To those who registered as walkers in Chicago and the virtual walkers across the country, thank you so much for participating in this event. A big “thank you” also goes to those who donated in support of Team Second Wind, or in support of an individual walker. Without your support, we would not have been successful. These are just a few of the photos taken at the park. Of course, Midas, the Wonder Dog, Second Wind’s shortest but most enthusiastic Hiker, hiked along with Team Second Wind.
The Impact of regulation on lung transplantation:
Quality of care metrics is straightforward conceptually, but complicated in reality. The context must be considered to make sense of published data describing program performance. The primary metric used in lung transplantation is the one-year survival of all recipients in a given time period. Severity of disease, however, may establish the urgency of need for lung transplantation in the allocation system, but the impact on first-year survival is clearly a composite of multiple additional factors, not reflected in the allocation scoring (LAS) per se.

It is clear that this focus has consequences for candidate selection and dramatic resource implications. Programs must continually reconcile these issues for regulatory purposes.

Discussion
Governance in the health care sector in the United States is reliant on multiple agencies. A regulatory imperative is accepted for high-risk clinical fields. Safe practices should be promoted and monitoring of programs is conventionally recognized. Solid organ transplantation in the US has evolved with multiple challenges and become a field with exemplary accountability and recognition of regulatory principles. Lung transplantation is a particularly hard-pressed subspecialty and outcome metrics are applied to monitor performance. The realities of the regulatory imperative, however, have specific pros and cons that influence daily decision making in transplant programs.

The quality parameters and specific outcome metrics may have become inadvertent drivers in this complex process. It is unclear if equity is served best with current arrangements.

Donor lungs meanwhile remain a truly scarce commodity and not all patients listed will actually receive the transplants they need in time.

The quality metrics currently applied and reported for performance monitoring in solid organ transplantation are a subject of some debate. The validity of measures and the categorization of such metrics especially in lung transplantation may require some review.

The Lung Allocation Score was intended to improve equity in the process of lung transplantation. It has now become the primary selection factor, with decimals deciding between recipients. Equity achieved at the time of implementation is now subject to external forces and unintended consequences. In summary, the impact of regulation on clinical practice, the administrative workload and incurred financial burden for lung transplant programs is mounting.

(Reservation continued from page 5)

(President continued from page 5)

participated as a Charity Partner with the Respiratory Health Association in the Hike for Lung Health. Second Wind was able to fund-raise $7,150.00 of which $5,132.40 went to the Financial Assistance Fund and the remaining went to the organizers of the Hike for Lung Health for lung health research, education and expenses for putting on the Hike. As we have stated before, this fundraiser was our only fundraising event for the year. The money raised by Second Wind will go into our Financial Assistance Fund. Effective January 1, 2019, Board Member Patrick Henry will become the Chairperson of the Financial Assistance Program.

800 Help Line - Beginning January 1, 2019, Second Wind will no longer have a toll-free Help Line. Currently, the Help Line rings into my home and will continue to do so until the end of the year when I retire. Email addresses will be provided so members may contact Board Members with any questions.

We hope all of you are well. Please get a flu shot if you haven’t already done so. Even with almost fourteen years post-transplant, I still wear a mask when I go to the doctor’s office or to Cleveland Clinic.

Loyola Medicine Marks 30th Anniversary of Groundbreaking Lung Transplant Program

by Jim Ritter
Media Relations, Loyola University Medical Center
jritter@lumc.edu

MAYWOOD, IL – Loyola Medicine’s groundbreaking lung transplant program has reached a new milestone, marking the 30th anniversary of its first lung transplant.

Loyola has performed nearly 950 lung transplants. This is more than four times as many lung transplants as the combined total of all other centers in Illinois combined, according to the federal government’s Organ Procurement & Transplantation Network.

"The 30th anniversary is a testament to the commitment of the medical center and the dedication of an outstanding lung transplant team," said Jeffrey Schwartz, MD, surgical director of lung transplantation.

(Please see Regulations continued on page 12) (Please see Anniversary continued on page 16)
Reintroducing Board Member
Tom Nate

The Board of Directors for Second Wind Lung Transplant Association, Inc. is pleased to announce its newest Board Member, Mr. Thomas Nate of Bandera, Texas. Mr. Nate was first elected to the Association's Board of Directors at the first annual meeting of the Board on January 5, 2016. In the spring of 2017, Tom resigned his position on the board due to some personal challenges but has now rejoined the board having taken care of those issues.

Tom received a bilateral lung transplant at Barnes Jewish Hospital in St. Louis, MO, on May 3, 2007 after being diagnosed with Kartagener Syndrome and Bronchiectasis. Approximately eight months after his transplant he was diagnosed with chronic rejection. Tom received a second bilateral lung transplant, again at Barnes Jewish Hospital, on September 20, 2010.

Tom sought re-election to the Board of Directors for the following reasons:

I am interested in serving Second Wind and the Lung transplant community and am applying for one of the vacant positions on the board of Second Wind Lung Transplant Association.

Since my first Bi-lateral lung transplant and recovery, I have actively sought opportunities to mentor and support other lung transplant patients both pre and post-transplant. Having been a participant in the Barnes Jewish Hospital Transplant Mentor training, I have stayed involved each year including continuing to mentor transplant patients while I was in chronic rejection and even through the wait for my second bi-lateral lung transplant. I have been blessed to be called upon to mentor long distance patients, like myself to help them overcome their fears of moving towards taking the transplant journey.

I have also spoken at churches, bible study groups and respiratory therapists groups sharing my story and experiences with them. I have been active with Donate Life Texas to spread the word on the importance of organ donation and sign up new donors.

I am currently 8 years post on my second bilateral lung transplant and have been blessed with excellent health and minimal issues since my second transplant surgery. I have found myself wanting to find ways to give more back to the transplant community in return for the blessings I’ve been given. I have maintained my annual membership in Second Wind Lung Transplant Association of St Louis and participate in their Lung Walk fundraiser when travel and my calendar allow. I have also recently begun to attend transplant support group meetings at University Hospital in San Antonio.

Transplant News from UNOS
Writing to your Donor Family

UNOS has outlined the steps to get started for writing to a donor family. Every transplant center has different policies and procedures for contacting donor families and recipients to protect the privacy of both parties.

To start with, you should call your transplant coordinator and explain that you want to write a Thank You note to your donor family. Find a card that is beautiful and peaceful. Write your note when you are feeling positive but be sure to have someone else read it to be sure what you write is what you mean.

Write in your own handwriting, if possible, and remember your note is anonymous. Please write as soon as you are able, don’t put it off, as it will help the grieving family of the donor to know that their family member helped others.

Avoid including any specific information about yourself (age, where you live) or your family. Don’t include the name of your surgeon or your transplant center.

UNOS suggests you include the following: Awareness of the donor family’s loss; how very grateful you are for their loved one’s donation; something simple and general about yourself and your family (hobbies and other interests); how long you were on the transplant waiting list; the difference the transplant made e.g. in how you feel, what you’re now able to do.

For most transplant centers you will give it to your lung transplant coordinator. Your Center will forward the letter to their local Organ Procurement Organization (OPO). Both someone at the transplant center and the OPO will read the letter to be sure that there is no identifying information in your letter.

UNOS states it is impossible to know if the donor family will reply to your card or letter. If the donor family does reply, the OPO will continue to forward your letters back and forth. If a day comes when both you and the donor family want to communicate directly, the OPO will guide you in that process.

(Editor note: you may find it very helpful to have someone carefully proofread your letter before sending it out since right after transplant you are on numerous medications that can alter your perception of what you want to say and how to say it. My son read mine and found I had written something that could have been very hurtful and I had to really twist my thinking to see it; so he rewrote it to say and mean what I wanted to share with my donor family).
Generous Strangers Create Miracles by Patrick Henry
Board of Directors, Second Wind Lung Transplant Assoc. Inc.

I had lunch with a miracle the other day. Oh, she looked ordinary enough, and the other restaurant patrons may not have paid much attention to the attractive, energetic woman in animated conversation with me, but if they knew what I did, they might have stared in wonder.

The miracle, the wonder of her, if you will, is the fact that she was there at all. It is a miracle born of modern medicine, of her determination and the support of family and friends, but most importantly, of a series of selfless decisions made by people she will never know.

Born with a condition that left her lungs defenseless against the mildest of environmental assaults, my friend Holly was in serious decline by her late thirties. Doctors had done their best to get her that far, and she had led a nearly normal life, but they couldn’t stop the inevitable. Unless something changed, she was going to slowly suffocate to death. Then, because of the ultimate act of charity by a stranger, Holly received a double-lung transplant.

In addition to the skill of her medical team and that stranger’s gift of life, Holly’s continued presence in our lives is also the result of strict adherence to a lifelong regimen of powerful immunosuppression drugs and an obsessive vigilance against infections of any sort. Her dogged efforts in this regard demonstrate great respect for the gift she received.

Long-term survival rates for double-lung transplant recipients are still uncertain—only approximately 50% live beyond five years—but Holly has beaten those odds. She is in year sixteen, and making the most of her new, post-transplant life.

She works hard as the Volunteer Coordinator for a local family services agency, plays a pretty decent game of tennis (she and a partner medaled in Doubles at the U. S. Transplant Games) and is a dynamo in whatever she tackles.

As well as helping to improve her community, Holly provides critical emotional and physical support to her husband, David, a man who was there to provide the same for her when she was facing her health crises. In one of those bittersweet ironies, the universe seems so fond of, Dave’s condition was becoming more serious just as Holly’s was becoming less so, and this gave her the opportunity to return his loving favors.

And for me personally, someone who also suffers from a serious lung condition, Holly’s example of how to cope with it while preparing for the possibility of something as risky and frightening as a major organ transplant, has been invaluable. She has been my role model and mentor.

As I sat there at lunch that day, I couldn’t help but wonder what would have happened if the family of the person whose lungs now live inside her had not consented to the organ donation. In the midst of their own grief they were called upon

(Regulations continued from page 10)

A new bill aiming to potentially reduce some of the established regulatory complexity may be on the horizon. Proponents of The Regulatory Accountability Act 2017 cite potentially less time consuming and costly agency rules related advantages of such de-regulation. The Act is likely to make regulation initiatives by federal agencies, including health related authorities, more difficult. There is considerable uncertainty as to how such new legislation will affect the rigor of scientific process underlying current rulemaking and associated established standards.
NEW MEMBERS
Cynthia Abi Gerges
Marsha Bakken
Edward Kuhn
Kelley Morgan
Debbie Ray
Ed Smiley
Pchai Suryanarayan
Paul Albert
Jerry Gray
Donna Markell
Lisa Potter
Levorn Ross
Kay Spence

During the months July, August, and September we had new members and renewals who asked to be coded as confidential. We would like for all of you to know that we do not share your information with anyone unless we have your written permission to do so. By being "confidential" we can't list you as a new member, when you renew your membership. We also can't list your transplant anniversary date. Thank you!

MEMBERSHIP RENEWALS
Kathryn Bryan
Robert E. Courtney
Robert Glim
Eric Harned
Denise Jacobs
Donna Lacey
Mindy Meyers
Timothy Monahan
Lola O'Brien
Sandy Patton
Indira Ramichan
Carla Sworcor
Robert Tharp
Gail E. Weadon
Diana Wenzel
Paul Woods
Marc Chelap
Mary Jo Festle
Harlan Halvorson
Matthew Hill
Jane Kurz
Maria Loss
Beth Mitchell
Garry Nichols
Tim O'Leary
Ernest Pemberton
Margaret Seantor
Samuel Tambyrajha
Fred Walker
Patrick Weber
Reana Woods

POLICY FOR HONORARY MEMBERSHIPS
It is the Policy of Second Wind Lung Transplant Association, Inc. to recognize Members as Honorary Members in the following cases:
- Those Members who have been Members of the Association for more than 20 years; or,
- Those Members of the Association that are more than 20 years post-transplant, independent of the number of years such Member has been a Member of the Association.

Honorary Members will be recognized as such by publication of their status in AirWays, on the Email Support Group and on the Association's Facebook page. In addition, annual dues of the Association, if any, will be waived in perpetuity.

As of this newsletter covering the period up to March 2018, there are eight (8) members who newly qualify for honorary membership. Congratulations!

Donations to Second Wind Lung Transplant Association
The Board of Directors expresses appreciation to the following people for their financial support of Second Wind. Thank you very much for your donations, they are most appreciated!

General Fund
Robert E. Courtney
Mary Jo Festle
Jane M. Kurz
Robert E. Courtney
Michele O'Guinn
Samuel Tambyrajha
Gail E. Weadon
Paul D. Woods

Membership Fund*
Donald H. Gwynne
Garry Nichols
Samuel Tambyrajha

* Membership Fund provides for waiver or reduction in membership dues for those with limited financial resources.

Financial Assistance Fund
Kathryn B. Bryan
Karen Couture
Hike for Lung Health Fundraiser - $5,132.40.
Donna Lacey
Garry Nichols

We would also like to thank also those confidential members who made a donation to the Financial Assistance Fund.

Notice: It is the Policy of Second Wind Lung Transplant Association, Inc. to prohibit the posting of any email and/or message regarding the exchange of medications on any communication medium of the Association.

Support Groups & Event Calendar Policy
AirWays posts coming events that are of interest to our readers. Please submit the name of the event, location, date(s), time(s), website link, contact person, and a short description of the event if needed. We are not able to include fundraisers.

Closing dates are the end of the months of January, March, May, July, September, and December. Due to printing and mailing schedules, please submit items for publication at least two weeks before the closing date.
Organ Transplantation and Your Mouth

If you are an organ transplant patient, you are at risk for serious mouth problems. Your medical condition and side effects from your transplant medications can affect your oral health and complicate dental care. This fact sheet identifies problems you may encounter and explains how you can help keep your mouth healthy.

PRE-TRANSPLANT DENTAL CHECK-UP
A dental check-up is an important part of your pre-transplant evaluation. Because some medications you take after transplant can cause problems in your mouth, you want your mouth to be as healthy as possible before your transplant procedure. Taking care of cavities, periodontal (gum) disease, and any other mouth problems ahead of time can help prevent or reduce the side effects of transplant medicines. Keeping your mouth clean and free of dental disease is important for your general health as well.

POST-TRANSPLANT DENTAL CARE
Anti-rejection medications suppress your immune system and make it easier for you to develop infections and other problems in your mouth, including:

- Dry mouth – the "cotton mouth" feeling you get when you don't have enough saliva to keep your mouth moist. Dry mouth increases your risk for tooth decay.
- Mouth ulcers – sores in the soft lining of the mouth that can make chewing, speaking or swallowing painful.
- Infections – such as gum disease that can harm the tissues holding the teeth in place, or thrush, a fungus infection that appears as creamy white patches in the mouth.
- Gingival overgrowth – enlarged gums that cover part of the teeth, making brushing and flossing difficult and increasing the risk for bleeding and infection.
- Tumors – mouth cancers that occur in some transplant patients, especially those who have smoked.

Once your transplant has stabilized, your dentist can treat new dental disease and help you manage any side effects of transplant medication that may occur. All mouth problems should be treated.

It's important for your dentist and your transplant doctor to speak with each other before dental treatment. Together, they will work out a dental care plan that safely meets your needs. For example, they may decide that you need to take antibiotics before dental treatment, or your doctor may adjust your medication.

- Make sure your dentist knows that you are a transplant patient. Give your dentist the contact information for your transplant doctor.
- Bring a list of all your medications, including over-the-counter drugs, to every dental appointment. Remember to tell your dentist if your medications have changed.
- Talk to your dentist about your general health. If you have diabetes or other health conditions, make sure your dentist knows. In the same way, talk to your transplant doctor about your oral health. Tell your doctor if you have mouth problems.

KEEPING YOUR MOUTH HEALTHY
You can do a lot to keep your mouth healthy after your transplant procedure. Look inside your mouth daily and check how it feels with your tongue. Side effects from medications may show as white or red patches, sores, ulcers, or tumors. You may notice dryness in your mouth, a lump, or bleeding gums when you brush. Call your dentist if you notice any changes or problems.

Brush and floss every day. Good daily oral hygiene is vital to keeping your mouth healthy. If you have any questions about brushing and flossing, particularly if your mouth is sore, ask your dentist or dental hygienist.

REMEMBER...

- Have a dental check-up before your transplant procedure.
- See your dentist regularly after your transplant has stabilized.
- Call your dentist when you notice any problem or change in your mouth.
- Take care of your mouth every day.

National Institute of Dental and Craniofacial Research
National Oral Health Information Clearinghouse
1 NOHICWay
Bethesda, MD 20892-3500
(301) 402-7364
www.nidcr.nih.gov
Support Groups & Events Calendar

Lung Transplant Support Groups.
Dover Campus, St. Clare’s Health System
400 West Blackwell Street, Dover (Morris County), NJ
For information, call (732) 412-7330

Cincinnati Support Group
Second Thursday of each month at 6:30pm, hosted at the home of Robert and Cynthia Lohstroh; 4120 Beamer Ct., Cincinnati, OH 45246. Phone: (513) 752-0451.
Covers Cincinnati, Dayton, and Northern Kentucky.

St. Louis Second Wind Lung Transplant Association
Second Wind of St. Louis is now available on Facebook by searching that name.
Second Sunday of each month, 2pm, at Chris’ Pancake and Dining. Contact person: Amanda Helderle, (314) 225-6751 may12usch@yahoo.com

Loyola University Medical Center
Pre-transplant, post-transplant patients, & support person(s).
First Tuesday every month, 11 AM - 12:15 PM
Third Tuesday every month, 6:30 PM
All meetings: EMS building, 3rd floor, Rm 3284
2160 S. First Ave, Maywood, IL 60153
For information, contact Susan Long (708) 216-5454 slong@lumc.edu

Emory Lung Transplant Support
First Monday of the month at 12 noon on the Emory Campus.
Location Changes. Contact Julia Buckst at jsbuckst@gmail.com for more information

Shands Hospital Lung Transplant Support Group
Shands Cancer Hospital, South Tower, 5th Floor
1515 SW Archer Rd., Gainesville, FL 32610
Contact: Micki Luck, nodurm@shands.ufl.edu
Phone: (352) 519-7545

University of Washington Medical Center Seattle, WA
Support groups meets the second Tuesday of the month between 12:30 and 2:30 PM in a conference room off the cafeteria. Many people meet in the cafeteria to have lunch before the meeting. Contact person is Angela Wagner, email wagnera@uw.edu

Pre- and post-transplant Support Group
UWMC patients, their family and friends. Meetings are on the second Tuesday of the month, 12:30-2:30.
Contact: Angela Wagner, MSW at (206) 598-2676; wagnera@uw.edu www.uwltsg.org

University of California San Francisco
Lung Transplant Support Group, Third Thursday of every month, 1-2:30 pm, 505 Parnassus Ave., Room 1015. Moffitt San Francisco, CA 94143-0307 Contact: Andrea Baird, LCSW Andrea.Baird@ucsf.edu / (415) 353-138

St. Joseph’s Hospital & Medical Center
Lung Transplant Support Group
500 W. Thomas Rd., Phoenix, AZ 85013
2nd Tuesday of every month, 11:45 am - 1:00pm
Mercy Conference Room Contact: Kathy Lam, LCSW
Kathy.Lam@DignityHealth.org Phone: (602) 406-7009

University of Chicago Medical Center
Lung Transplant Support Group for transplant recipients and those who are listed. Third Wednesday of every month, 5-6:30 pm.
Center for Care and Discovery (CCD),
7th Floor Conf.Rm. 7710
5700 S. Drexel Ave., Chicago, IL 60637
Contact: Fran Hammon, LCSW
frances.hammon@uchospitals.edu or call (773) 702-4608 Pager 6720

St. John Medical Center
A Second Chance Lung Transplantation Support Group
26908 Detroit Rd. Second Floor Conference Room
Westlake, Oh 44145
Second Tuesday of most months 6-8pm
Group Discussion: Recipients, Caregivers, & Families
Contact Kathy Lewis (kathy2lungs@yahoo.com)

University of Texas Southwestern
Transplant Support Group
St. Pauls Auditorium, 5939 Harry Hines Blvd.,
Dallas, TX 75390.
Pre-lung transplant patients and caregivers are also welcome.
Contact: Jodie C. Moore, MSN, RN, ACNP-BC
jodie.moore@utsouthwestern.edu Phone: (214) 645-5505

Second Chance for Breath Lung Support Group
St. Lukes Medical Center
2900 West Oklahoma Ave., Milwaukee, WI 53201
For pre & post lung transplant patients
Contact Person: Ed Laskowski
laskowskiedward@att.net or call (414) 231-3013

Ohio State University Lung Transplant Support Group
Comprehensive Transplant Center
770 Kinnear Road, Columbus, OH 43212
For directions assistance call: (614) 293-8000 medicalcenter.osu.edu
Please call our office with any questions at (614) 293-5822 Meeting last Tuesday of the Month 6:00 p.m. to 7:30 p.m.

UCLA Lung Transplant Support Group
Ronald Regan UCLA Medical Center
757 Westwood Plaza Drive, Los Angeles, CA 90095
8-120 Conference Room
12:00 to 1:30 pm
Stephanie Aguirre, MSW, ACSW Phone: (310) 267-9728
saguirre@mednet.ucla.edu
(Anniversary continued from page 10)

Daniel Dilling, MD, medical director of lung transportation, noted that relatively few centers worldwide have performed lung transplants for as long and as successfully as Loyola. “We have been on the cutting edge throughout the decades, and we continue to push the envelope to help more people,” Dr. Dilling said.

Loyola performed the first lung transplant in Illinois in 1988. In 1990, Loyola cardiothoracic surgeon Mamedou Bakhos, MD, performed the state’s first double-lung transplant. Other milestones include a simultaneous double-lung and kidney transplant (2007), five lung transplants in just over 24 hours (2014) and a successful lung transplant on a 74-year-old patient (2015).

Last year, Loyola performed its first lung transplant using ex vivo lung perfusion. This groundbreaking technology evaluates and treats donor lungs before transplant, potentially increasing the supply of donor lungs.

Loyola’s multidisciplinary lung transplant team regularly evaluates and successfully performs transplants in patients who have been turned down by other centers in Chicago and surrounding states. Despite taking on more challenging cases, Loyola consistently records outstanding outcomes.

The lung transplant program is part of Loyola’s advanced lung disease program, which offers second opinions and leading-edge clinical trials. The advanced treatment can in some cases delay or even eliminate the need for a lung transplant.