Message from the Section Chief

We would like to take this opportunity to convey significant enhancements in patient care and education at Tulane University Medical Center and the Southeast Louisiana Health Care System in New Orleans, occurring at the onset of this academic year. This newsletter also includes important clinical trials that you may wish to consider for your patients. We look forward to partner with you by serving as a tertiary referral center for your patients.

Joseph A. Lasky, MD
Professor of Medicine
Deming Educational Fund Chair of Internal Medicine
Chief, Section of Pulmonary Diseases, Critical Care & Environmental Medicine

Grace Anne Dorney and her husband Ted Koppel have made a heartfelt donation to provide for a Pulmonary and Cardiac Rehabilitation Center at Tulane. The Grace Anne Dorney Pulmonary and Cardiac Rehabilitation Center offers crucial care for people with pulmonary or cardiac conditions. The center is conveniently located on the seventh floor of the main hospital at Tulane Medical Center’s downtown campus.

Appointments can be made by calling 504-988-1791.

Grace Anne Dorney is the current President of the COPD Foundation and their gift to Tulane is founded on their first-hand experience that pulmonary rehabilitation is transformative to the lives of people with COPD.

A link highlighting Grace Anne Koppel’s work can be found on this site: https://medlineplus.gov/magazine/issues/fall14/articles/fall14pg2-4.html

Pulmonary rehabilitation has demonstrated physiological, symptom reducing, psychosocial, and health economic benefits in multiple outcome areas for patients with chronic respiratory diseases. As such, it should be a standard of care alongside other well-established treatments for patients with a chronic respiratory disease.
Tulane HCA Opens the Grace Anne Dorney Pulmonary and Cardiac Rehabilitation Center (cont.)

Comprehensive Pulmonary and Cardiac rehab care plans include:

- A physical activity program designed to increase overall fitness and improve breathing.
- Education on lung and heart disease and how to manage it. We may offer tips for eating right and staying active. We can also assist with smoking cessation.
- Techniques to help people conserve energy in daily life.
- Breathing strategies, to help you manage symptoms and breathe as easily as possible.
- Counseling or a support group, to help cope with the stress and challenges related to lung and heart limitations.

Patient testimonials from Tulane’s Grace Anne Dorney Rehab Center:

“I’m living life with a better outlook.”

“I started Pulmonary Rehab and have noticed a huge difference in my activities. These activities may be considered small for some but for me they are big. The first thing I noticed, I was unable to reach into my freezer because it is located above the refrigerator and always had to ask my children to help me which was frustrating. Now I can actually reach higher with my arm and get into my own freezer and I don’t have to ask my family and it makes me feel more independent.”

“They have given back my confidence and reassurance that I had previously lost from my condition and I am forever grateful for them. I have noticed that my energy has drastically increased. I find myself able to walk faster and longer doing the things that previously drained me. I am able to go shopping on my own and complete all of errands without relying on others help. I no longer feel the weight and guilt of always asking for help. Lastly, the staff has been extremely patient with my education and are helping me understand my condition and learn other objectives that I wanted to learn. They have helped me with my nutrition to gain my weight back, how to take my pulse, proper breathing techniques for when I feel short of breath, and allowed me to better comprehend my disease.”

Now after just 12 sessions at cardio/pulmonary rehab, I have noticed a big difference in my energy and mental confidence. I no longer stay in bed. I enjoy going shopping and finding things to do with my husband. The weights have helped me build strength and I am able to reach and carry things easier. My exercise has increased tremendously and now I feel much better. My brother is even looking into getting me a bike, which is exciting.
Dr. Kheir received his medical degree from University of Balamand, Lebanon, and completed his fellowship training, along with a Master of Science in Clinical Research and Medical Education, at Tulane. He is board certified in Internal Medicine, Pulmonary Disease and Critical Care Medicine. He joined Tulane faculty as an Assistant Professor of Clinical Medicine in 2013 and has been both prolific in clinical research and recognized for excellence in teaching.

Recently, Dr. Kheir completed an Interventional Pulmonary Fellowship at the combined program of Beth Israel Deaconess Medical Center and Massachusetts General Hospital, two major teaching hospitals of Harvard Medical School. His clinical and research interests include endoscopic lung volume reduction, pleural disease and complex airway diseases.

He has distinguished himself as the recipient of the American Association of Bronchology and Interventional Pulmonology (AABIP) research award for two consecutive years, and is currently involved in multiple innovative multicenter trials including the two listed here for which he is the overall Principal Investigator:

- **Airway Stents for Excessive Dynamic Airway Collapse:** A randomized placebo controlled trial to evaluate the safety and efficacy of short term employment of stents in patients with severe excessive dynamic airway collapse to evaluate the safety and efficacy of this modality.

- **Fibrinolytic Therapy versus Medical Thoracoscopic for the Treatment of Pleural Infection:** A randomized clinical trial to compare two currently accepted standard-of-care treatment strategies: Medical thoracoscopy as compared to instillation of intrapleural tissue Plasminogen Activator (TPA) and human recombinant Deoxyribonuclease (DNase) for the management of pleural infections in adults (complicated parapneumonic effusions or pleural empyema)

Dr. Kheir is looking forward to enrolling patients from within our region into these two important trials.

For patient's referral, please contact:

**Dr. Fayez Kheir**

504-988-3896
fkheir@tulane.edu
Tulane Adult Cystic Fibrosis Program Update

Tulane’s adult CF program is growing as we strive to improve upon our state-of-the-art comprehensive care and access to cutting edge therapies for this population. Our efforts to enhance patient care has been recognized by the CF Foundation, Vertex Pharmaceuticals, and the Dean of Tulane Medical school. We have received several grants and awards and we have expanded our clinical team to include the following new members:

- A full-time CF social worker and mental health coordinator, Mandy Wilson, LCSW. In addition to providing comprehensive social work services, we now screen and treat every patient for anxiety and depression. This effort is funded by a 3-year $150,000 grant from the CF Foundation.
- A CF outpatient clinical pharmacist, Alex Rock, Pharm D. Each patient’s complex medical regimen is reviewed by our pharmacist. This is funded by a 3-year $150,000 grant from the CF Foundation.
- A CF exercise physiotherapist, Christian Dirosa, CEP. This effort is funded by a 1-year $32K award from Vertex Pharmaceuticals called the “CF Circle of Care Award. In this program, we will be systematically assessing body composition and exercise capacity of each patient followed by goal-setting and formal recognition of accomplishments.

In research, we have several ongoing pharmaceutical and investigator initiated clinical trials:

- Nontuberculous Mycobacterial Infections and the Public Water Supply in the Greater New Orleans Area. Sponsored by a $25K intramural grant from the Dean of Tulane School of Medicine. This is in collaboration with the Tulane School of Public Health and Tropical Medicine as well as the National Public Health Research Institute at Rutgers University
- VX14-661-107 A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Evaluate the Efficacy and Safety of VX-661 in Combination with Ivacaftor in Subject Aged 12 Years and Older With Cystic Fibrosis, Heterozygous for the F508 del CFTR Mutation and Not Likely to Respond to VX-661 and/or Ivacaftor Therapy (F508del/NR)
- VX14-661-110 A Phase 3, Open-Label, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment With VX-661 in Combination with Ivacaftor in Subjects Aged 12 years and older With Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation
- VX15-371-101: A Phase 2a, Randomized, Double-blind, Placebo-controlled Incomplete Block, Crossover Study to Evaluate the Safety and Efficacy of VX-371 in Subjects aged 12 Years or Older With Cystic Fibrosis, Homozygous for the F508del-CFTR Mutation, and Being Treated with Orkambi
- VX16-661-114: Phase 3b, Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Assess the Safety, Efficacy, and Tolerability of Tezacaftor/Ivacaftor (TEX/IVA) in an Orkambi-experienced Population Who Are Homozygous for the F508del-CFTR Mutation
- VX16-445-001 A Phase ½ Study of V-445 in Health Subjects and Subjects with Cystic Fibrosis
- Cystic Fibrosis Patient Registry. This is an invaluable source of searchable data in which all of our CF patients clinical, social, and demographic information is compiled and can be analyzed to further improve our care.

Last year we were recognized by the CF Foundation with a “Quality Improvement Award” for our efforts.

Find us on our website:
http://www2.tulane.edu/som/departments/medicine/pulm
dis/lung-center/cystic-fibrosis/index.cfm

For referral to our comprehensive CF program or clinical trials please contact:
Sandy Ditta
Senior Research Administrator
504-988-4040
sditta@tulane.edu
The past two years have witnessed a significant burst of activity in the critical care arena for our section, led by the work of Drs. Nielsen and Halvorson:

- We successfully launched the Tulane University Critical Care Project (http://tulane.ccproject.com/), a branch of the ATS award winning Critical Care Project family of websites. This open access education platform provides access to video of critical care themed lectures delivered here at Tulane, along with monthly lists of the best pulmonary and critical care journal articles as selected by our fellows, links to other critical care themed educational materials, and soon, editorials on the intensive care mindset and training from ICU specialists from around the country and Europe.

- Dr. Nielsen was appointed an Editor for the Concise Critical Appraisals section of the eNewsletter of the Society for Critical Care Medicine (http://enews.sccm.me/category/concise-critical-appraisal/). Working with the Pulmonary and Critical Care fellows as co-authors, he submits eight reviews of highly relevant, potentially practice-changing journal articles annually. Full reviews are available to members of SCCM members through the society’s official website.

- Dr. Halvorson, as Chief Editor, compiled a comprehensive on-line critical care reference for the Tulane house staff: the Tulane ICU Handbook. This handbook is designed to serve as an up-to-date, literature based, easily accessed referenced for house staff rotating through the ICUs at the SE Louisiana VA, Tulane Hospital, and University Medical Center New Orleans. The handbook will be available through the Tulane Critical Care Project website (http://tulane.ccproject.com/), which means it will be available to learners worldwide as well!

- Dr. Nielsen recently returned from serving as an instructor at the inaugural Haitian Acute and Emergency Care Conference at the newly opened St. Luke’s Hospital in Port au Prince, Haiti. Over 100 Haitian physicians and nurses attended the two-day conference, a combination of lectures and hands-on practical sessions, with topics ranging from airway management to ultrasonography to sepsis identification and management. Based upon the success of this initial conference (which was featured in the Haitian national press as well as by the US State Department), this is now anticipated to become an annual event, and Dr. Nielsen is already involved in planning next year’s program!

As you can see, section faculty members are contributing to academic and service activities in critical care on the local, national and international stages, and we are involved in additional projects that we look forward to sharing with you in the future! For more information on new or current activities, please contact Dr. Nielsen at nnielsen@tulane.edu.
The Southeast Louisiana Veterans Health Care System (SLVHCS) in New Orleans Opens

The Southeast Louisiana Veterans Health Care System (SLVHCS) replacement Medical Center in New Orleans opened its doors in December 2016. Over the course of the last 6 months, all outpatient clinics, urgent care, and radiology have moved over to the new site. Since Hurricane Katrina, Tulane University Medical Center has been providing Veteran Inpatient Services. Come August 2017, Inpatient care will transition over a six-month period, to the new facility.

Once open, the new Medical Center will boast 120 medicine/surgery beds including an observation unit in the Emergency Department, 24 ICU beds (mixed medicine/surgery/cardiac, closed-model), 20 acute psychiatric beds, and 60 transitional living beds including 40 physical rehab focused and 20 palliative focused. Exciting care that can now be provided in-house, previously outsourced, includes PET (positron emission tomography) scans, Interventional Radiology, and Advanced Bronchoscopy.

Medical Education is a high-priority of this VA and it has two major academic medical affiliations including Tulane University. We have smart classrooms, conference rooms, integrated cameras in procedure rooms, and wireless technology to facilitate this mission. There is also an entire building with 130,000 square feet and 15 lab groups to support research. Dr. Halvorson has two active IRB-approved studies within the Pulmonary Department at the VA.

Tulane University Pulmonary, Critical Care, and Sleep Medicine Faculty are the staff for the SLVHCS’ Section. Sleep was the first Department to activate in the new VA. We perform not only Polysomnography, but advanced sleep evaluations including Multiple Sleep Latency Testing. The VA has two Interventional Pulmonologists and plan to perform very specialized procedures in the VA facility including Rigid Bronchoscopy. Also, starting this year, we will perform Cardiopulmonary Exercise Testing (CPET). SLVHCS will become the main southern referral center within the VA (east of Houston and west of Atlanta) by 2018, we expect a high volume of procedures such as EBUS to come from this.

Pulmonary and Critical Care Fellows will have the opportunity to work outside MICU services and provide care for patients admitted to the Cardiac Care Unit and Surgical Intensive Care Unit as well, thus broadening their scope of learning. We have new state-of-the-art point-of-care ultrasounds from GE, point-of-care bronchoscopes from Storz, as well as ventilators by Maquet, with neurally-adjusted-ventilatory-assist capability.

Tulane University is thrilled about their partnership with SLVHCS. Tremendous things are on the horizon for our Veteran population in New Orleans.
Enrolling Clinical Studies

The Tulane Pulmonary Section is offering several clinical trials, registries and support groups available for patient participation. Currently there are trials open to enrollment for patients with idiopathic pulmonary fibrosis, cystic fibrosis, scleroderma, rheumatoid lung, and pulmonary hypertension due to interstitial lung disease. Some of the trials that are open for enrollment are listed below. Should you need additional information please contact:

- **Sandy Ditta, Senior Research Administrator**
  504-988-4040
- **Christine Glynn, RN/Clinical Research Coordinator**
  504-988-0743
- **Kristen Lingle, RN/Clinical Research Coordinator**
  504-988-2325

### Pulmonary Fibrosis

- A Phase II open label study to evaluate the effect of GBT440 on hypoxemia in subjects with Idiopathic Pulmonary Fibrosis (IPF) who are using supplemental oxygen at rest (ZEPHIR). This trial will determine whether GBT440 reduces the requirement for supplemental oxygen, via enhancing binding affinity to hemoglobin.

- **TRAIL1**: A Phase 2 Study of Safety, Tolerability and Efficacy of Pirfenidone in Patients With Rheumatoid Arthritis Interstitial Lung Disease.

- Comparison of Transbronchial, Cryoprobe and VATS Biopsy for the Diagnosis of Interstitial Lung Disease

- Pulmonary Fibrosis Foundation Patient Registry Protocol

- Idiopathic Pulmonary Fibrosis Prospective Outcomes (IPF-PRO) Registry

- Pulmonary Fibrosis Support Group Meeting Second Wednesday of the Month

### Pulmonary Hypertension

- A Multicenter, Randomized, Double-Blinded, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of Inhaled Treprostinil in Subjects with Pulmonary Hypertension due to Parenchymal Lung Disease

### Scleroderma

- A double blind, randomized, placebo-controlled trial evaluating efficacy and safety of oral nintedanib treatment for at least 52 weeks in patients with Systemic Sclerosis associated Interstitial Lung Disease (SScILD)

- (GRASP)-Genome Research in African American Scleroderma Patients

### Cystic Fibrosis

Please refer to the Cystic Fibrosis Program Update in this newsletter.