Idiopathic pulmonary fibrosis (IPF) is a chronic disease of the lungs that results in slowly progressive scarring, and the cause is not known. IPF typically strikes patients who are older than 50 years of age, and is more common among men than women. All races are susceptible to IPF worldwide. In the United States the rate of new cases is about 50 – 100 new patients per year for every million people.

The symptoms of IPF at the onset are usually mild shortness of breath with exertion such as hurrying on the level or carrying packages. Most patients experience a dry cough without producing any sputum. There is great variability in the course of IPF among different patients, but most people do get worse. The average time of survival from the time a physician makes the diagnosis of IPF is quite variable, but in large series of cases half will have died within 3 – 5 years; some patients survive for decades while others deteriorate quite rapidly.

There is no known effective treatment for IPF, and good therapy is needed badly. Supportive care with oxygen, exercise, cough suppressants, and similar measures is often helpful in relieving symptoms but does not reverse the scarring process. Although several forms of therapy have been used to treat IPF over the past three decades, none have been shown clearly to be effective in randomized placebo-controlled trials. A recent study sponsored by the US National Institutes of Health (PANTHER) showed no benefit and substantially increased risks from treatment with azathioprine / prednisone / N-acetyl cysteine (NAC); the placebo vs NAC arm of that trial continues. Fortunately there has been a lot of new interest in treatment for IPF. Within recent years approximately 5 studies with new drugs have been completed and 6 studies with different drugs are currently under way.

The Vermont Lung Center is currently enrolling patients with IPF in 5 different clinical trials led by VLC investigators Yolanda Mageto, MD and Gerald S. Davis, MD. All trials require that patients have well-documented IPF and no other conditions that might complicate their course. Three trials limit age to 75 or 80 years, while two have no age limits. These trials test a variety of new concept drugs designed to block the formation of scar tissue at the level of signals within or between cells. The current trials each last about 1 year and involve visits to the Center once per month for testing.

**The trials are:**
- Celgene CC-930, an oral tablet to block JNK, an intracellular signal; all subjects receive drug after the first month
- Fibrogen FG-3019, an intravenous monoclonal antibody against Connective Tissue Growth Factor; all subjects receive active drug IV once per month at various dose levels.
- ImmuneWorks IW-001, an oral liquid of Type V collagen; all subjects receive drug at various dose levels.
- Intermune Pirfenidone (ASCEND), an oral tablet 3 times per day; subjects randomized 1:1 drug:placebo, with assured drug (open label) after 1 year.
- Boehringer BIBF-1120, an oral tablet 2 times per day; subjects randomized 2:1 drug:placebo.

Potential patients or their health care providers should contact the VLC at 802-847-LUNG or 802-847-2193. There is great hope that new treatments will offer real improvement for patients with this serious and usually progressive lung disease.

**Computed Tomography Scan of Idiopathic Pulmonary Fibrosis**

HRCT scan at the level of the heart shows a pattern of small irregular shadows at the periphery of the lungs.
Interested in Volunteering?

Things to know.

1) The Vermont Lung Center staff is responsible for making sure you know what is expected of you in regards to the study.

2) Once the study is explained to you, you will be asked to read and sign an "Informed Consent". This form is designed to explain everything you need to know about the study.

3) Studies may be therapeutic (involving observation of lung function). However The Vermont Lung Center can make no claims that your involvement in a research study will improve your condition.

4) Compensation may or may not be provided to you for your involvement in a study. If compensation is provided, it is meant to cover your time and expenses incurred--it does not constitute employment.

If you are interested in finding out more about volunteering for a research study, please call us at (802) 847-2193

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New Faces at the Vermont Lung Center

Bridget Shea

What do you do at the Vermont Lung Center?
My official title at FAHC is "research dietitian", but I am a research coordinator on the medical ICU.

Where did you grow up?
I grew up in Shelburne, Vermont

Where did you go to school?
High school at Champlain Valley Union HS
Undergraduate degree in biology from the University of New Hampshire
Graduate degree in nutrition and food sciences from the University of Vermont
Dietetic internship at Brigham and Women's Hospital in Boston, MA.

Why did you choose to live in Vermont?
I grew up here and have always loved Vermont. Living in Boston for a year really showed me that I am not a city girl at all! I love living in such a beautiful place and the seasons and all of the outdoor activities that are possible in Vermont (skiing, hiking and camping are some of my favorites) make it an ideal home for me. I'm also a foodie and I love the local foods in Vermont, especially fresh veggies, artisan breads and cheeses and good coffee!

What is your favorite thing about working in research?
I enjoy research because its fun to learn new things all of the time and being part of studies that have the potential to improve patient care or change medical practice is exciting. I like the emphasis on continued learning, the atmosphere of curiosity and collaboration, and the genuine interest in each other's research endeavors I see amongst colleagues here at the VLC.

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Olga Sideleva

What do you do at the Vermont Lung Center?
Postdoctoral Research Fellow, studying relationships between asthma and obesity. I am trying to determine connections between inflammation in adipose tissue and lung function, and the role of bronchial epithelial cells in obese asthma.

Where did you grow up?
Eastern Siberia, Lake Baikal (world's greatest freshwater lake). I grew up in a "scientific reservation", which included Irkutsk State University and nine academic institutions called "Akademgorodok"; situated deep in the woods, only students and crazy scientists walking around.

Where did you go to school?
St. Petersbug State University, Russian Federation. Founded in 1725, it's the first Russian University, home of Pavlov's dogs, Periodic Table of Chemical elements and Nobel Prize in Physics which brought to life "wireless connection".
My first degree – equivalent to the Master of Science in animal genetics second degree – PhD equivalent, is a project about genetic predisposition to atopic bronchial asthma.

Why did you choose to live in Vermont?
Burlington reminds me a lot about my childhood: oligotrophic lake, mountains, small "academically oriented" community. I am happy that my children will have their childhood memories very similar to mine, except it's in a different language.

What is your favorite thing about working in research?
Two things: ideas and people. Working on a project is like falling in love over and over again, through passion, regret, hard work, excitement, madness and hope, all at the same time. There is nothing better than to be surrounded by people who live the same crazy life. It's incredible to see the success of the molecular medicine these days and be a part of it.

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Can the use of a nasal wash improve my asthma?
Daily use of nasal saline irrigation has been shown to improve sinusitis, quality of life and reduce the use of medications. Whether it in turn improves asthma is as yet unknown but would be expected.

What about the use of a humidifier?
The presence of a humidifier in homes has been linked to asthma in children. It is thought that use of a humidifier provides a friendly environment for molds and dust mites so humidifier use is generally discouraged.
### List of Current VLC Studies

#### ASTHMA

**Asthma Patient Registry (APR)**
- **Primary Investigator:** Charles Irvin, Ph.D., Director, Vermont Lung Center
- **Coordinator:** Stephanie Burns
- **Who:** Anyone with a physician diagnosis of asthma
- **What:** 1 visit lasting approximately 30 minutes
- **Compensation:** none

**A Randomized, Placebo-Controlled Pilot Study of Pioglitazone for the Treatment of Moderate to Severe Asthma in Obese Asthmatics (GLITZ)**
- **Primary Investigator:** Anne Dixon, M.D.
- **Coordinator:** Laurianne Griffes
- **Who:** Adults with a BMI of 30-60 with poorly controlled asthma
- **What:** 5 visits and one phone call over 13 weeks
- **Compensation:** up to $170

**The Study of Soy Isoflavones in Asthma (SOYA)**
- **Primary Investigator:** Charles Irvin, Ph.D., Director, Vermont Lung Center
- **Coordinator:** Stephanie Burns
- **Who:** Adults and Children 12 years and older with symptomatic asthma
- **What:** 9 visits over 24 weeks
- **Compensation:** up to $400

**Study of Asthma and Nasal Steroids (STAN)**
- **Primary Investigator:** Anne Dixon, M.D.
- **Coordinator:** Stephanie Burns
- **Who:** Adults and Children 6 years and older with rhinitis or sinusitis and asthma
- **What:** 10 visits over 6 months
- **Compensation:** up to $350

**STAT Signaling in Allergic Lymphocytes**
- **Primary Investigator:** Sean Diehl, Ph.D.
- **Coordinator:** Stephanie Burns
- **Who:** Asthmatics and Non-Asthmatics ages 12 - 60
- **What:** Up to 2 visits
- **Compensation:** up to $100

**Relationship between BMI and Immune Cell Function**
- **Primary Investigator:** Anne Dixon, M.D.
- **Coordinator:** Laurianne Griffes
- **Who:** Premenopausal Female Asthmatics and Non-Asthmatics ages 18 and older
- **What:** 1 visit
- **Compensation:** $10

**Assessing the Effects of Lung Volume and Time on Airway Responsiveness in Asthmatic Subjects**
- **Primary Investigator:** Jason Bates, Ph.D.
- **Coordinator:** Laurianne Griffes
- **Who:** Asthmatics and Non-Asthmatics ages 18 and older
- **What:** 2 visits
- **Compensation:** $25 per visit

#### IDIOPATHIC PULMONARY FIBROSIS (IPF)

**ImmuneWorks: A Phase 1, Open Label, Multi-Dose Study to Evaluate the Safety, Tolerability, and Biologic Effects of Three Doses of IW001 in Patients with Idiopathic Pulmonary Fibrosis (IPF)**
- **Primary Investigator:** Yolanda Mageto, M.D.
- **Coordinator:** Patti Lutton
- **Who:** People with Idiopathic Pulmonary Fibrosis
- **What:** 8 visit plus one phone call over 6 months
- **Compensation:** Mileage over 20 miles one way

**FibroGen: A Phase 2a, Open-label, Single-Arm Study to Evaluate the Safety, Tolerability, and Efficacy of FG-3019 in Subjects with Idiopathic Pulmonary Fibrosis**
- **Primary Investigator:** Yolanda Mageto, M.D.
- **Coordinator:** Patti Lutton
- **Who:** People with Idiopathic Pulmonary Fibrosis
- **What:** Treatment every 4 week for 24 weeks, follow up visits every 4 weeks through week 44.
- **Compensation:** up to $560

### CYSTIC FIBROSIS

**Management of Bacterial Air Contamination in Cystic Fibrosis Clinics**
- **Primary Investigators:** Laurie Leclair, M.D./Thomas Lahiri, M.D.
- **Coordinators:** Joan Lippmann/Sandra Diehl
- **Who:** People with Cystic Fibrosis
- **What:** IV infusions every 3 weeks for 45 weeks, 2 follow up visits through week 54.
- **Compensation:** None

**A Phase 3, Multi-center, Multinational, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Efficacy and Tolerability of MP-376 Inhalation Solution (Aeroquin) Given to Stable Cystic Fibrosis Patients**
- **Primary Investigators:** Laurie Leclair, M.D./Thomas Lahiri, M.D.
- **Coordinators:** Joan Lippmann/Sandra Diehl
- **Who:** People with Cystic Fibrosis
- **What:** 6 visits over 70 days
- **Compensation:** Up to $550

**A Phase 3, Open-label, Randomized Trial to Evaluate the Safety and Efficacy of MP-376 Inhalation Solution (Aeroquin™) Versus Tobramycin Inhalation Solution (TIS) in Stable Cystic Fibrosis Patients**
- **Primary Investigators:** Laurie Leclair, M.D./Thomas Lahiri, M.D.
- **Coordinators:** Joan Lippmann/Sandra Diehl
- **Who:** People with Cystic Fibrosis
- **What:** 8 visits over 182 days
- **Compensation:** Up to $800

**The Use of Nasally Delivered Pulmozyme in the Treatment of Sinusitis in Cystic Fibrosis Patients: A Pilot Study**
- **Primary Investigator:** Thomas Lahiri, M.D.
- **Coordinators:** Sandra Diehl
- **Who:** People with Cystic Fibrosis
- **What:** 6 visits over 1 year
- **Compensation:** none

### SARCOIDOSIS

**A Phase 2, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled Study Evaluating the Safety and Efficacy of Treatment with Ustekinumab or Golimumab in Subjects with Chronic Sarcoidosis**
- **Primary Investigator:** Gerald Davis, M.D.
- **Coordinator:** Laurianne Griffes
- **Who:** People with Chronic Sarcoidosis
- **What:** Treatment every 4 week for 24 weeks, follow up visits every 4 weeks through week 44.
- **Compensation:** up to $560
The flu is caused by influenza viruses. These tiny organisms spread when people sneeze. The virus can last several hours on a surface or on your hands (if you don’t wash them), and it there’s an outbreak it is almost impossible not to be exposed. These viruses invade your nose and airways, and cause sneezing, coughing, sore throat, body ache and high fevers. The flu viruses can cause pneumonia and even death.

The good news is that there’s a very effective way to stop you from getting the flu. That’s to get vaccinated. Why do we have to get vaccinated every year? For many things we need to be vaccinated only every few years. The reason we need the flu vaccine so often is that the flu virus changes from year to year. So if you’ve got an infection or a vaccination one year, it’s not going to protect you from the flu the next year. Scientists and physicians have to figure out how the flu virus changes from year to year, and based on this, a different flu vaccine is recommended each year. The vaccine usually contains a mixture which will protect you against 3 forms of different flu viruses.

What leads to major break outs of flu like the “Swine Flu” we had a couple years ago? That virus arose from genes of a human virus mixing with genes from a swine virus. This can happen because the influenza viruses are able to infect human and pigs (and birds). Some of the genes from that virus originally came from the major flu pandemic that occurred in 1918, and killed millions of people world-wide (“The Spanish Flu”).

So far it looks like we’re gearing up to face a regular flu season. That means anyone with respiratory disease should get vaccinated. There will still be plenty of other viruses, other than the flu virus, circulating this winter. That means you can still get colds and coughs. The best way to protect yourself from these other viruses is to stay away from people when they are sick, and to be careful about hand washing.

Stay healthy this winter!

Get Your Flu Shot Now!

Anne Dixon, MD
Tai Chi

Tai Chi Chuan is an ancient Chinese gymnastic, which consists of a series of graceful movements that utilize all joint and muscle groups. More importantly, it uses breathing techniques, patterns and specialized breathing exercises. Tai Chi addresses one’s breathing, as well as the musculoskeletal system, in a moderate manner. It has been empirically shown over millennia, and recently scientifically, that Tai Chi is exceptionally well tolerated by the elderly and people with chronic impairments of health, including lung problems. Many of these people find substantial satisfaction and health benefits with Tai Chi training (e.g., improved stamina, balance, etc.).

People with chronic obstructive lung disease and other chronic lung problems experience significant life impairment. This is due in part to shortness of breath and general deconditioning. Pulmonary rehabilitation programs offer methods of improvement for both. However, many programs address muscle strength more than breathing patterns and they can be dependent on equipment availability. Tai Chi Chuan offers an important addendum to the traditional rehab. It addresses the breathing and muscle function in an equal and moderate fashion. It also does not require any specific equipment or large spaces to be practiced.

In our current research project we are assessing the effect of Tai Chi on the well-being and function of people with COPD who are undergoing pulmonary rehabilitation as well as the feasibility and applicability of Tai Chi training in the rehabilitation of Vermonters with COPD. The new information obtained through this research may be an important addendum to current rehabilitation programs since incorporating Tai Chi could add an exercise modality which doesn’t require special facilities or machines (can be done at home), can be performed at the persons’ individual pace and convenience and addresses breathing patterns in a gentle but effective way.
CF CORNER

Laurie Whittaker Leclair, MD

Fletcher Allen Health Care’s Cystic Fibrosis Clinical Research Center Refunded!

Since 2006 the CF center at FAHC has received funding from the CF Foundation to participate in multi-center clinical trials of new therapies to treat CF. Since 2008 the CF center has been a part of the therapeutic and development network (TDN), an organization of 77 CF centers across the US, under the leadership of the University of Washington, with expertise in CF-related clinical trials. Inclusion in the TDN clinical trials network is competitive and the FAHC center received notice in January that their funding and participation will be continued for another year. The grant supports the necessary local personnel to accomplish phase II-IV clinical trials in the area of CF. Notable recent studies include new anti-inflammatory treatments and small molecules targeted at correcting defects in CF transmembrane conductance regulator, the abnormal protein in CF. Drs. Laurie Leclair and Tom Lahiri are the co-investigators on the grant and Joan Lippmann and Sandra Diehl are the CF research coordinators.

NEW CLINICAL RESEARCH STUDIES FOR IDIOPATHIC PULMONARY FIBROSIS Gerald Davis, MD

New research studies are becoming available at the Vermont Lung Center (VLC) for the treatment of idiopathic pulmonary fibrosis (IPF; lung scarring of unknown cause). IPF is a chronic lung disease that strikes older adults (average age 64 years), and affects men slightly more commonly than women. Patients experience gradually progressive shortness of breath and a dry cough. Some patients develop fatigue, weakness, poor appetite, weight loss, and general debility, but many do not. The median survival after diagnosis (half of the patients alive) is about 3 – 5 years, but many do not. The median survival after diagnosis (half of the patients alive) is about 3 – 5 years, but many do not. The median survival after diagnosis (half of the patients alive) is about 3 – 5 years, but many do not. The median survival after diagnosis (half of the patients alive) is about 3 – 5 years, but many do not.

1). A trial sponsored by Fibrogen, Inc tests the effectiveness of a monoclonal antibody FG-3019 directed against Connective Tissue Growth Factor (CTGF), a hormone-like material made in the lung that is believed to promote lung fibrosis. The drug is given intravenously every 3 weeks for one year. All patients enrolled will receive active drug (no placebo or inactive drug treatment). Other medications for IPF are permitted.

2). A trial sponsored by Celgene will test CC-930, a drug that inhibits signaling within cells through the c-Jun N-terminal kinase (JNK) pathway, a system believed to accelerate collagen production. The drug is given as an oral tablet. Patients will receive the active drug or a look-alike inactive placebo tablet for four weeks, and then all will receive the active drug for the rest of the year. Low doses of prednisone are permitted but other IPF treatments are not.

3). A research study of IW001, a drug that affects the formation of a specific kind of lung scar tissue is sponsored by Immuneworks. The medication – colla-gen type V – is taken daily as an oral liquid. All patients will receive active drug in low, moderate or higher doses for 6 months. No other IPF drugs are allowed.

4). We expect to open a fourth trial sponsored by InterMune to test the effectiveness of pirfenidone for IPF. The drug is directed against a signaling compound called Transforming Growth Factor-beta (TGF-β). It is an oral tablet taken daily for one year. Patients will be assigned randomly in equal numbers to receive the active drug or an inactive placebo. Pirfenidone has been approved for the treatment of IPF in Japan and Europe.

More information about all of these trials can be obtained through the Vermont Lung Center or at www.clinicaltrials.gov. We are very excited that after years of little attention there are now many opportunities and new hope for patients with IPF.
### Spring 2010

#### List of Current VLC Studies

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**Ask Dr. Charlie**

**How many other people have asthma?** Asthma affects some 17 million Americans including 6.3 million children. Asthma is the most common chronic disease of childhood.

**Does asthma effect the growth and development of the lung?** A study from Denmark 20 years ago suggested that asthma stunted the growth of lungs in children. Later studies show that even minimal treatment regimens allow the lungs to grow normally.
STAT! Do immune cells from allergic asthmatics make decisions differently?

Sean Diehl, PhD

When the immune system attacks allergens it makes a substance called immunoglobulin E or IgE. In allergic people in general, this IgE sets off a chain reaction that leads to watery eyes and runny noses. In allergic asthmatics, IgE can be dangerous because this chain reaction can also cause lung airway narrowing, which makes breathing difficult. There is research showing that “sopping” up IgE is beneficial for many asthmatics, but the focus of my study is to see how the immune system “decides” to make IgE in the first place.

STATs are molecules inside immune cells that tell an immune cell whether to make IgE or not. It is known that there are two types of STATs: some that tell an immune cell to turn on IgE and other STATs that tell the immune system to turn it off. In the STAT study we will check blood samples to determine which kinds of STATs are turned on in the immune cells of allergic asthmatic patients versus non-asthmatic controls. We hope that this information will give us ideas about new drugs to develop which will turn on the “right” STATs and bring the IgE into balance for the long-term health of allergic asthmatics.

Asthma is a common disease. About 20 million people in the United States live with asthma. However, not everyone knows that there are two main types of asthma. These two types are called allergic asthma and non-allergic asthma. About half of all asthma patients have allergic type and the other half have the non-allergic type. Allergic asthma is made worse with pollen or pet hair or even some foods. Non-allergic asthma is made worse by cold air, exhaust smoke, or exercise. But the most interesting part is that even though both allergic and non-allergic asthma affect the lungs, the cell types involved are different. Allergic asthma involves the immune system, which is many types of cells working together to patrol our bloodstream and organs to protect us against invaders. Although the immune system is good at fighting off viruses and bacteria, it can get confused and attack allergens–harmless things that cause allergies (like pet dander or pollen, for example).
Cystic Fibrosis and Inhaled Antibiotics  

Charlotte C Teneback MD

In patients with cystic fibrosis (CF) changes in the lungs lead to thick sputum which becomes colonized with bacteria. In many adults with CF a particular organism called *Pseudomonas* often lives in the lung chronically. This contributes to loss of lung function and leads to acute exacerbations of infection which require oral or intravenous antibiotics. Along with various forms of airway clearance and other medications such as dornase alpha (Pulmozyme) that help clear mucous out of the lungs, inhaled antibiotics have been developed to try to suppress the growth of bacteria. These medications help improve lung function and reduce the frequency of exacerbations.

Inhaled antibiotics are taken through a nebulizer, usually two to three times a day, and can take half an hour or more to administer. Inhaled antibiotics are usually used on an alternating basis. A month of treatment is followed by a month of no treatment, or treatment with a different inhaled antibiotic in order to reduce the risk of the bacteria becoming resistant. Currently inhaled antibiotics are only available against *Pseudomonas*, not other bacteria such as MRSA.

The first inhaled antibiotic available was colistimethate, or colistin. However, use of this has largely been replaced by inhaled tobramycin (Tobi) after this became available in the late 1990s. In the past year a new inhaled antibiotic called aztreonam (Cayston) has also become available and has offered an alternative to patients who have not been able to tolerate tobramycin.

Excitingly, several more inhaled antibiotics are currently being developed and tested for patients with CF. Here at the Vermont Lung Center, we recently participated in a trial of Tobramycin Inhaled Powder (TIP), which uses a different formulation of tobramycin that can be inhaled much more quickly than the currently available liquid form. Enrollment in this trial has completed and we are awaiting the results.

We are currently participating in two clinical trials using an inhaled version of levofloxacin, a frequently prescribed anti-pseudomonas drug used in CF. Several additional inhaled antibiotics, in earlier stages of testing, are coming down the pipeline as well.

In the past 15 years, the use of inhaled antibiotics has helped people with CF improve their lung function and decrease the number of exacerbations (requiring oral or iv antibiotics, and often hospitalization). The recent FDA approval of inhaled aztreonam (Cayston) has provided an additional treatment option, along with the previously available colistin and inhaled tobramycin. The development of inhaled antibiotics is rapidly continuing, with the goal of developing effective therapies that can be administered quickly to help people with CF stay healthy.
The University of Vermont Cystic Fibrosis Center recently completed a clinical research study to examine the effects of various medications that are harmful to the kidney. The majority of patients with cystic fibrosis (CF) receive a number of medications that may result in chronic kidney disease over the course of their lifetime. Two therapies which are recommended include certain antibiotics and high dose ibuprofen, both of which have been demonstrated to cause both acute and chronic kidney disease. We collected urine specimens from children and young adults, ages 3 to 25 years. Certain chemical signals, called biomarkers, can be measured in the urine and are a sign of damage to the kidney. The biomarkers that were examined in this study are called KIM-1 and NAG, as well as urine protein levels, another sign of kidney damage. About half the subjects were receiving chronic high dose ibuprofen, a therapy that may help to preserve lung function in patients with CF. Results will also be analyzed to look at the effect of treatment with certain antibiotics called aminoglycosides. Data analysis is pending.

**CF CORNER**

**Thomas Lahiri, MD**

The University of Vermont Cystic Fibrosis Center recently completed a clinical research study to examine the effects of various medications that are harmful to the kidney. The majority of patients with cystic fibrosis (CF) receive a number of medications that may result in chronic kidney disease over the course of their lifetime. Two therapies which are recommended include certain antibiotics and high dose ibuprofen, both of which have been demonstrated to cause both acute and chronic kidney disease. We collected urine specimens from children and young adults, ages 3 to 25 years. Certain chemical signals, called biomarkers, can be measured in the urine and are a sign of damage to the kidney. The biomarkers that were examined in this study are called KIM-1 and NAG, as well as urine protein levels, another sign of kidney damage. About half the subjects were receiving chronic high dose ibuprofen, a therapy that may help to preserve lung function in patients with CF. Results will also be analyzed to look at the effect of treatment with certain antibiotics called aminoglycosides. Data analysis is pending.

**A New Face at the Vermont Lung Center-Patti-Lutton**

**What do you do at the Vermont Lung Center?**

Clinical Research Coordinator – working with patients who participate in IPF trials.

**Where did you grow up?**

I grew up in Underhill Center, Vermont

**Where did you go to school?**

I earned a BA at University of Vermont and previously went to Champlain College where I earned an Associate in Science degree.

**Why did you choose to live in Vermont?**

I was born in Vermont. And though I thought about leaving, I stayed here because it’s a beautiful state, a nice place to raise a family.

**What is your favorite thing about working in research?**

My favorite part of research is working with the study participants. It is their willingness to be in studies that bring us closer to finding answers to treating illnesses such as IPF.

**Ask Dr. Charlie**

**Charles G. Irvin, PhD**

The heat and humidity is making my asthma worse. Is this real? What should I do?

Heat, humidity compared to cold, dry conditions in general decreases the chance of an asthma attack but the heat increases the rate of breathing and so increases the sensation of difficulty in breathing. Hot, humid conditions favor pollen formation so stay inside and enjoy the AC.

I hear placebo (sugar) tablets cure asthma. Is this true?

No, probably not but two studies (and one was our ALA TAPE study) have shown that placebo treatments improve asthma symptoms; however, lung function is not improved.
## List of Current VLC Studies

### ASTHMA

<table>
<thead>
<tr>
<th>Study</th>
<th>Primary Investigator</th>
<th>Coordinator</th>
<th>Who</th>
<th>What</th>
<th>Compensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma Patient Registry (APR)</td>
<td>Charles Irvin, Ph.D., Director, Vermont Lung Center</td>
<td>Stephanie Burns</td>
<td>Anyone with a physician diagnosis of asthma</td>
<td>1 visit lasting approximately 30 minutes</td>
<td>none</td>
</tr>
<tr>
<td>A Randomized, Placebo-Controlled Pilot Study of Pioglitazone for the Treatment of Moderate to Severe Asthma in Obese Asthmatics (GLITZ)</td>
<td>Anne Dixon, M.D.</td>
<td>Laurianne Griffes</td>
<td>Adults with a BMI of 30-60 with poorly controlled asthma</td>
<td>5 visits and one phone call over 13 weeks</td>
<td>up to $170</td>
</tr>
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<td>The Study of Soy Isoflavones in Asthma (SOYA)</td>
<td>Charles Irvin, Ph.D., Director, Vermont Lung Center</td>
<td>Stephanie Burns</td>
<td>Adults and Children 12 years and older with symptomatic asthma</td>
<td>10 visits over 6 months</td>
<td>up to $350</td>
</tr>
<tr>
<td>Study of Asthma and Nasal Steroids (STAN)</td>
<td>Anne Dixon, M.D.</td>
<td>Stephanie Burns</td>
<td>Asthmatics and Non-Asthmatics ages 12 - 60</td>
<td>2 visits</td>
<td>up to $100</td>
</tr>
<tr>
<td>STAT Signaling in Allergic Lymphocytes</td>
<td>Sean Diehl, Ph.D.</td>
<td>Stephanie Burns</td>
<td>Asthmatics and Non-Asthmatics ages 18 and older</td>
<td>1 visit</td>
<td>up to $10</td>
</tr>
<tr>
<td>Relationship between BMI and Immune Cell Function</td>
<td>Anne Dixon, M.D.</td>
<td>Laurianne Griffes</td>
<td>Premenopausal Female Asthmatics and Non-Asthmatics ages 18 and older</td>
<td>2 visits</td>
<td>$25 per visit</td>
</tr>
<tr>
<td>Assessing the Effects of Lung Volume and Time on Airway Responsiveness in Asthmatic Subjects</td>
<td>Jason Bates, Ph.D.</td>
<td>Laurianne Griffes</td>
<td>Asthmatics and Non-Asthmatics ages 18 and older</td>
<td>1 visit</td>
<td>$25 per visit</td>
</tr>
<tr>
<td>Culture of Nasal Epithelial Cells in Respiratory Disease</td>
<td>Anne Dixon, M.D.</td>
<td>Laurianne Griffes</td>
<td>Asthmatics and Non-Asthmatics ages 18 and older</td>
<td>1 visit</td>
<td>$25 per visit</td>
</tr>
</tbody>
</table>

### IDIOPATHIC PULMONARY FIBROSIS (IPF)

<table>
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<tr>
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</tr>
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<tr>
<td>ImmuneWorks: A Phase 1, Open Label, Multi-Dose Study to Evaluate the Safety, Tolerability, and Biologic Effects of Three Doses of IW001 in Patients with Idiopathic Pulmonary Fibrosis (IPF)</td>
<td>Yolanda Mageto, M.D.</td>
<td>Patti Lutton</td>
<td>People with Idiopathic Pulmonary Fibrosis</td>
<td>8 visit plus one phone call over 6 months</td>
<td>Mileage over 20 miles one way</td>
</tr>
<tr>
<td>FibroGen: A Phase 2a, Open-label, Single-Arm Study to Evaluate the Safety, Tolerability, and Efficacy of FG-3019 in Subjects with Idiopathic Pulmonary Fibrosis</td>
<td>Yolanda Mageto, M.D.</td>
<td>Patti Lutton</td>
<td>People with Idiopathic Pulmonary Fibrosis</td>
<td>45 weeks of treatment followed by 52 weeks of observation</td>
<td>None</td>
</tr>
<tr>
<td>Celgene: A Phase 2, Sequential, Ascending Dose Study To Characterize The Safety, Tolerability, Pharmacokinetic And Biological Activity Of CC-930 In Idiopathic Pulmonary Fibrosis (IPF)</td>
<td>Yolanda Mageto, M.D.</td>
<td>Patti Lutton</td>
<td>People with Idiopathic Pulmonary Fibrosis</td>
<td>56 weeks of treatment followed by 52 weeks of observation</td>
<td>Up to $1,050</td>
</tr>
</tbody>
</table>

### CYSTIC FIBROSIS

<table>
<thead>
<tr>
<th>Study</th>
<th>Primary Investigator</th>
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<th>Who</th>
<th>What</th>
<th>Compensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of Bacterial Air Contamination in Cystic Fibrosis Clinics</td>
<td>Laurie Leclair, M.D./Thomas Lahiri, M.D.</td>
<td>Joan Lippmann/Sandra Diehl</td>
<td>People with Cystic Fibrosis</td>
<td>6 visits over 70 days</td>
<td>Up to $550</td>
</tr>
<tr>
<td>The Use of Nasally Delivered Pulmozyme in the Treatment of Sinusitis in Cystic Fibrosis Patients: A Pilot Study</td>
<td>Thomas Lahiri, M.D.</td>
<td>Sandra Diehl</td>
<td>People with Cystic Fibrosis</td>
<td>6 visits over 1 year</td>
<td>none</td>
</tr>
</tbody>
</table>

### SARCOIDOSIS

<table>
<thead>
<tr>
<th>Study</th>
<th>Primary Investigator</th>
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<td>A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Safety and Efficacy of Treatment with Ustekinumab or Golimumab in Subjects with Chronic Sarcoidosis</td>
<td>Gerald Davis, M.D.</td>
<td>Laurianne Griffes</td>
<td>People with Chronic Sarcoidosis</td>
<td>Treatment every 4 week for 24 weeks, follow up visits every 4 weeks through week 44.</td>
<td>none</td>
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</tbody>
</table>
Cytomegalovirus (CMV) in Critically Ill Patients

Julie Martin, RD

Cytomegalovirus (also called CMV) is a common virus that infects people of all ages. According to the Centers for Disease Control and Prevention, between 50% and 85% of people in the United States have been infected with CMV by the time they are 40 years old. The older you are, the higher the chance that you have had a CMV infection.

CMV infections are rarely serious in healthy people. Most people who are infected with CMV have no signs and symptoms. Mild fatigue is the most common symptom and it generally lasts only a few weeks. CMV is generally only a problem for certain high risk groups, such as unborn babies whose mothers become infected with CMV during the pregnancy or people whose immune systems have been weakened by disease or drug treatment (as with organ transplants). A new area of research is looking at CMV in patients who are critically ill and in an intensive care unit.

After a person has had a CMV infection, the virus usually lies dormant (or inactive) in the body, but it can be reactivated during times of stress or illness. It is suspected that if the virus is reactivated in critically ill patients that it may make them even more ill, worsening their lung function.

A new research study sponsored by the National Institutes of Health is being conducted at Fletcher Allen Health Care by Dr. Polly Parsons and Dr. Renee Stapleton. This study is looking at critically ill patients that it may make them even more ill, worsening their lung function.

The Vermont Lung Center is supported in part by the following organizations:

- American Lung Association of Vermont
- ACRC Network
- National Institutes of Health
- National Center for Research Resources

Non-Profit Org.
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Permit No. 143
Asthma afflicts approximately 11 million Americans including 3.8 million children. Asthma is responsible for 5,000 deaths each year in the U.S. But what exactly is asthma? How can it be treated?

We used to think that asthma was just “twitchy” airways. We thought that some people had sensitive airways that would contract in response to some stimulus in the air. But we now know that asthma is much more than that. The airways of people with asthma are inflamed: they can be red, swollen and have increased secretions in the airway causing severe narrowing and difficulty in getting air in and out of the lungs. In some people, the inflammation may be triggered by something in the atmosphere such as pollen, animal fur or just cold air, but in many people we do not know what first triggers their asthma. It can afflict people at any age, and can present with a wide range of symptoms: some people just have a troublesome cough. Others notice wheezing or shortness of breath when they go outside on a cold day.

It is important to have specialized breathing tests to confirm the diagnosis of asthma and follow the progress of the disease. Do you know how well your asthma is controlled? Are you at risk of having a serious asthma attack? These are questions your doctor can help you with.

How is asthma treated? Treatment usually consists of rescue and controller medication. Rescue medication (such as albuterol) is to be used when you get a sudden attack, ideally you should need this very infrequently. This sort of medication works to relax the muscles in the airway walls, but does nothing to prevent inflammation. The other type of medication that most people need is controller medication that acts as an anti-inflammatory, such as an inhaled steroid (e.g. Flovent ® or Pulmicort®).

The alarming news about asthma is that it appears many people are suffering with poorly controlled asthma. Our recent study of the flu vaccine, in which many of you participated, found that 28% of patients experienced an asthma exacerbation within 14 days of their clinic visit. This was similar to the findings of “Asthma in America”, a survey study conducted by the pharmaceutical company Glaxo-Smith-Kline. They found that 1 in 10 people with asthma are hospitalized within a 12 month period; 1 in 4 adults missed work within a 12 month period because of their asthma, and 1 in 3 people wake up at least once a week with asthma symptoms.

Asthma is out of control in the US: our goal at the Vermont Lung Center is to research new and innovative treatments to improve the control of asthma, so people with asthma can live their lives to the full.
Cardiopulmonary resuscitation, or CPR, is a medical procedure that is often used when a person’s heart or lungs stop working, for example during a cardiac arrest. CPR is a combination of shocks to the heart, chest compressions, artificial breathing, and special medicines for the heart. On TV and in the movies, people who get CPR usually survive. In real life, however, this isn’t the case; the outcomes after CPR are actually much worse than the media would lead us to believe.

Among all people who get CPR while in the hospital, only about 15% (or less than 1 in 7) survive to leave the hospital. Among patients with COPD and emphysema who use oxygen, and among those with advanced cancer, only about 1 in 20 patients survive to leave the hospital. Even if those patients do leave the hospital, their average lifespan is only about 3 months, and most patients spend that time in a nursing home. Therefore, CPR is probably not an appropriate procedure for many patients who are very ill.

Even though the outcomes after CPR are very poor and it rarely works, the medical culture in America is such that everybody gets CPR unless they specifically say they don’t want it. In other words, CPR is automatically provided to everyone whose heart or lungs stop working unless there is paperwork stating that they don’t want to receive CPR. To complicate things further, opting out of CPR for a patient is complicated. A health provider has to have a conversation with the patient about what CPR is and what the results of CPR are. They also need to talk about what things are important to the patient, what kind of quality of life is meaningful to the patient, and what the patient’s overall health care goals are. After all this is done, then the patient has to communicate their wishes to their loved ones and family members; so that if the patient is ever too sick to make his or her own decisions, someone they love and trust can carry out their wishes. Because all of these steps are hard to get into place and because doctors and patients are sometimes reluctant to start discussing these issues, we believe that a lot of people receive CPR when it either does not benefit them or they would have chosen not to receive it if they had more information.

With this in mind, our research group is especially interested in studying how we communicate about CPR and other end of life issues. We are currently conducting a study to gather the opinions on a particular communication approach about CPR with patients who have either COPD and use oxygen or have advanced cancer. We hope this research will help us understand how health care providers can improve their communication about CPR and provide better care to all patients.

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**CPR**

Cardiopulmonary resuscitation, or CPR, is a medical procedure that is often used when a person’s heart or lungs stop working, for example during a cardiac arrest. CPR is a combination of shocks to the heart, chest compressions, artificial breathing, and special medicines for the heart. On TV and in the movies, people who get CPR usually survive. In real life, however, this isn’t the case; the outcomes after CPR are actually much worse than the media would lead us to believe.

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**Interested in Volunteering?**

**Things to know:**

1) The Vermont Lung Center staff is responsible for making sure you know what is expected of you in regards to the study.

2) Once the study is explained to you, you will be asked to read and sign an “Informed Consent”. This form is designed to explain everything you need to know about the study.

3) Studies may be therapeutic (involving observation of lung function). However The Vermont Lung Center can make no claims that your involvement in a research study will improve your condition.

4) Compensation may or may not be provided to you for your involvement in a study. If compensation is provided, it is meant to cover your time and expenses incurred—it does not constitute employment.

If you are interested in finding out more about volunteering for a research study, please call us at (802) 847-2193.

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**The Vermont Lung Center is affiliated with the following organizations:**

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**The Spirogram**
Current Ongoing VLC Studies

ASTHMA

Asthma Patient Registry (APR)
Primary Investigator: Charles Irvin, Ph.D., Director, Vermont Lung Center
Coordinator: Stephanie Burns
Who: Anyone with a physician diagnosis of asthma
What: 1 visit lasting approximately 30 minutes
Compensation: none

A Randomized, Placebo-Controlled Pilot Study of Pioglitazone for the Treatment of Moderate to Severe Asthma in Obese Asthmatics (GLITZ)
Primary Investigator: Anne Dixon, M.D.
Coordinator: Stephanie Burns
Who: Adults with a BMI of 30-60 with poorly controlled asthma
What: 5 visits and one phone call over 13 weeks
Compensation: up to $170

The Study of Soy Isoflavones in Asthma (SOYA)
Primary Investigator: Charles Irvin, Ph.D., Director, Vermont Lung Center
Coordinator: Stephanie Burns
Who: Adults and Children 12 years and older with symptomatic asthma
What: 9 visits over 24 weeks
Compensation: up to $400

Study of Asthma and Nasal Steroids (STAN)
Primary Investigator: Anne Dixon, M.D.
Coordinator: Stephanie Burns
Who: Adults and Children 6 years and older with rhinitis or sinusitis and asthma
What: 10 visits over 6 months
Compensation: up to $350

STAT Signaling in Allergic Lymphocytes
Primary Investigator: Sean Diehl, Ph.D.
Coordinator: Stephanie Burns
Who: Asthmatics and Non-Asthmatics ages 12 - 60
What: Up to 2 visits
Compensation: up to $100

Do you or one of your family members have ASTHMA?

If so you may be able to participate in one of our asthma research studies at the Vermont Lung Center.

What are the Benefits of being in a Study?
* Gain a better understanding of your asthma
* Financial compensation provided

Who can participate in our studies?
* Children 6 – 17 and adults up to 70 (depending on the study)
* Physician diagnosed asthma
* Non-smoker (for at least 1 year)

If you are interested in learning more, please call us at: (802)847-2193 or e-mail us at Laurianne.Giffes@vtmednet.org or Stephanie.Burns@vtmednet.org

SARCOIDOSIS

A Phase 2, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled Study Evaluating the Safety and Efficacy of Treatment with Ustekinumab or Golimumab in Subjects with Chronic Sarcoidosis
Primary Investigator: Gerald Davis, M.D.
Coordinator: Laurianne Griffes
Who: People with Chronic Sarcoidosis
What: Treatment every 4 week for 24 weeks, follow up visits every 4 weeks through week 44.
Compensation: up to $560

IDIOPATHIC PULMONARY FIBROSIS (IPF)

Celgene: A Phase 2, Sequential, Ascending Dose Study To Characterize The Safety, Tolerability, Pharmacokinetic And Biological Activity Of CC-930 In Idiopathic Pulmonary Fibrosis (IPF)
Primary Investigator: Yolanda Mageto, M.D.
Coordinator: Joan Lippmann
Who: People with Idiopathic Pulmonary Fibrosis
What: 56 weeks of treatment followed by 52 weeks of observation
Compensation: Up to $1,050

ImmuneWorks: A Phase 1, Open Label, Multi-Dose Study to Evaluate the Safety, Tolerability, and Biologic Effects of Three Doses of IW001 in Patients with Idiopathic Pulmonary Fibrosis (IPF)
Primary Investigator: Yolanda Mageto, M.D.
Coordinator: Laurianne Griffes
Who: People with Idiopathic Pulmonary Fibrosis
What: 9 visits over 24 weeks
Compensation: up to $400

CYSTIC FIBROSIS

Management of Bacterial Air Contamination in Cystic Fibrosis Clinics
Primary Investigators: Laurie Leclair, M.D./Thomas Lahiri, M.D.
Coordinators: Joan Lippmann/Sandra Diehl
Who: People with Cystic Fibrosis
What: 6 visits over 70 days
Compensation: Up to $550

A Phase 3, Multi-center, Multinational, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Efficacy and Tolerability of MP-376 Inhalation Solution (Aeroquin) Given to Stable Cystic Fibrosis Patients
Primary Investigators: Laurie Leclair, M.D./Thomas Lahiri, M.D.
Coordinators: Joan Lippmann/Sandra Diehl
Who: People with Cystic Fibrosis
What: 6 visits over 70 days
Compensation: Up to $550

For more information on these studies, please visit our website @ www.vermontlung.org
People with lung disease often have bacteria living either intermittently or long-term within their airways. This is especially true for patients with cystic fibrosis (CF). CF is a genetic disease in which patients’ get progressive destruction of their airways from long term infections, particularly by the bacteria Pseudomonas aeruginosa. Current practices are focused on the prevention of spread of bacteria between patients however the best approach to accomplish this goal is not completely known. From prior studies we know that bacteria are spread by respiratory droplets and can be detected in the air after a routine clinic visit. Dr. Jonathan Zuckerman, a CF physician and researcher at Maine Medical Center, in conjunction with three other centers including the CF Center at Fletcher Allen Health Care, are performing a study to determine if the use of a mask during a CF clinic visit will decrease the shedding of bacteria into the air. Further, the study will also determine if shedding is more likely to occur during the measurement of lung function, where deep breathing and forced expiration is required. The study will also determine if when shedding does occur, how long it takes before the air is cleared of bacteria. The study, which is funded by the CF Foundation, is now active in the adult CF clinic and will start recruiting patients from the pediatric program early in 2011.