



Please join us for an open house tea!

To socialize and meet other parents having children with cystic fibrosis.

Sunday, January 26th
From 2pm—4:30pm

At the Holbrook Palmer Carriage House

Holbrook Palmer Park
150 Watkins Avenue, Atherton CA

Please bring a finger food item to share.

Please RSVP to Joanne Asano at
(650) 736-1905 by January 23rd.

**CYSTIC FIBROSIS
CENTER AT STANFORD**

Center Physicians

Richard Moss, Director; Noreen Henig, Adult Center Director; Carol Conrad, Terry Robinson, Lauren Witcoff

Important Phone Numbers

Clinic E Scheduling (Chandra McDuffie)	650-497-8841
Clinic E Fax	650-497-8837
Nicole Eden, Pediatric Nurse Coordinator.....	650-736-1359
Mary Helmers, Adult Nurse Coordinator.....	650-736-1358
Kristin Shelton, Respiratory Coordinator.....	650-724-0206
Julie Matel, Nutritionist, Dietitian	650-736-2128
Joanne Asano, Social Work.....	650-736-1905
Zoe Davies, Research Coordinator	650-498-5315
Colleen Dunn, Research Coordinator.....	650-736-0388
Janie Perez, Research Coordinator.....	650-723-5193
Judy Kirby, Webmaster	650-724-3474

For Urgent Issues

Monday–Friday 8:30–5:00 pm..... contact RN Coordinator
All Other Times (ask for Pulmonary Physician On-Call)..... 650-497-8000

Medication Refills Call pharmacy where medication was last filled

LPCH Pharmacy Refill Line

See our website at <http://cfcenter.stanford.edu> for more information about our center, CF and current topics.

To subscribe to this newsletter please email or call Judy Kirby at the number listed above.

Winter 2002

Cystic Fibrosis Center News



Brian Burks spent his last day as a 5-year-old in Stanford's General Clinical Research Center (GCRC) as a subject in a trial to test a new formulation of Tobi for children under age 6.

Winter 2002
Cystic Fibrosis
Center News

Clinical Research: We're All In This Together!

YOUR PARTICIPATION: OUR MOST VALUABLE RESOURCE

Only people with CF provide the most essential resource for discovery and delivery of advances in CF care—people with CF! The effectiveness and availability of new drugs, devices & treatments depend on having subjects to thoroughly test them. Clinical trials are long and arduous, involving scientists, pharmacists, clinicians, research coordinators and test subjects. As a member of the CFF Therapeutics Development Network (TDN) and as a major research center, Stanford concentrates on early stage Phase I and II trials of new drugs and devices. These trials determine crucial safety, dosing, mechanisms of action, and efficacy, setting the stage for broad Phase III trials that test how well a treatment works. Our team partners with other CF Centers in the TDN, pharmaceutical companies & bench scientists to discover & test new drugs, devices & treatments.

Stanford has a remarkable record of participation in clinical trials. In this issue we want to introduce you to the people who make up our team—the subjects, coordinators, research associates and behind-the-scenes staff who share a commitment to discovery of new treatments, and perhaps one day a cure to CF. We hope you will gain a better understanding of what clinical research is all about so that you, too, will join our team!



Lucile Packard Children's Hospital

STANFORD UNIVERSITY MEDICAL CENTER

CF Center at Stanford
701 Welch Road Suite 3328
Palo Alto, CA 94304



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For the Burks, Curing CF is a Family Affair

Accompanied by his mom Linda, and surrounded by two brothers and two sisters, Brian Burks spent his last day as a 5-year-old in Stanford's General Clinical Research Center (GCRC). He was a subject in a trial to test a new formulation of Tobi for children under age 6. He made the study's age cut-off by only one day! While Cara (21 months) slept in the corner, 3-year-old Kevin, 9-year-old Michael, and 8-year-old Rebecca joined Brian on his hospital bed, building towers. Rebecca couldn't resist testing Brian's math prowess to demonstrate the results of their home schooling. Though he's just in kindergarten, it took him only 3 minutes to come up with the answer to four to the fourth power—in his head! All of the Burks were wearing "Team CF" t-shirts earned at the CFF Great Strides walk last May.

This was Brian's second clinical trial. The first one involved two bronchoscopies at the age of 3. In this trial, following inhalation of the drug, Brian's vital signs were measured and his blood was drawn every two hours for eight hours. His mom said getting the IV started was the only hard part of the day. Brian added that it was a lot better than being in the hospital for real! Linda stated, "Without research, there won't be a cure. We have benefited tremendously from the people who were subjects of past studies. We hope Brian's participation will help people in the future as well."

Darcy Diaz is looking out for her Grandchildren

38-year-old Darcy Diaz was diagnosed at age 12, and has never been hospitalized. She has worked full time for the same law firm for 19 years, and exercises and inhales Pulmozyme every day. She has two children, both of whom carry one CF mutation. Darcy says she participates in studies for purely selfish reasons. "Someday my children will be ready to start families of their own and they may choose a spouse who is also a carrier. If a cure is found before that time, there will be no worries."

Darcy has participated in four trials, including the Phase I and II gene therapy trials. She has a "huge interest in science and participating makes me feel good." Despite having had 8 research bronchoscopies over the past few years, she says there has been little inconvenience, largely to the credit of an outstanding team at Stanford. She considers the relationships she has built with the research team are invaluable. When asked to summarize the philosophy that drives her decisions to become involved, Darcy adds, "There are very few times in one's life when you can make a difference. If everyone waited for someone else to do things, we would never get the necessary participation and ultimate result we are seeking."



OUR TEAM: ONLY THE BEST FOR OUR SUBJECTS

Our clinical research team is comprised of people from many disciplines and institutions across the country. Our physicians, nurses and research coordinators take an active role in protocol development, implementation and analysis of results. Their commitment to outstanding clinical care and meticulous research has earned the trust of the many families and people with CF who support our research. You may never meet many of the people involved in CF research, but they are there in the background, playing a pivotal role to ensure our subjects receive only the best care that results in exceptional clinical research!

Research coordinators manage the clinical trials process, preparing applications for Institutional Review Board approval, identifying, contacting and meeting with study participants and families, coordinating use of facilities & communicating with other team members to monitor trials. Zoe Davies, P.N.P., has worked with the Stanford CF Center for 10 years, following 6 years as a staff nurse. As a nurse practitioner, she performs physical examinations, administers treatments and monitors results. Colleen Dunn, RCP, made a transition to research coordinator after working in the LPCH pulmonary function laboratory for 9 years. Colleen recently completed the UC Clinical Trial Design and Management Certificate program. Her love of CF patients, and familiarity with the Stanford CF community is a tremendous resource to study participants, many of whom she's known and helped treat since they were diagnosed. Janie Perez, P.N.P., is the newest research coordinator who joined our team

after five years in the LPCH Health Van primary care outreach project and LPCH's high-risk infant development follow-up clinic.

Research Associates collect and analyze data, assist with trials and perform laboratory research on specimens obtained in the trials. Yao-pi Hsu staffs the Ross Mosier Laboratory for Cystic Fibrosis Research under the direction of Dr. Moss. The last 15 of her 32 years at Stanford have focused on CF, with particular study of the difference in cytokines and leukocytes between CF and normal subjects. This year, Wei Xiao, a pulmonologist from Shandong University School of Medicine in China has joined Yao-pi to learn more about CF research. Ilynn Nepomuceno De Freitas has been involved in CF research for 5 years, most recently leading the Health Buddy trial. Judy Kirby, R.N., developed and maintains the Center website (<http://cfcenter.stanford.edu>), manages the CFF reg-

Teen Allison Best Finds Time in a Busy Schedule

16-year-old Allison Best went to the national cheerleading competition last year with her Mountain View squad. She ice skates four hours and teaches ice skating three hours each week. She also takes Advanced Placement Biology in preparation for college. Until two years ago, she competed in ice skating, but there were too many other things she wanted to do in high school. Yet, she's participating in her second clinical trial in her spare time. This trial, known as the BILL study, involves taking a previously tested oral medication for 15 days, to determine its impact on inflammation. Allison hopes her efforts will result in new treatments or even a cure that will enable her and others with CF to lead much more normal lives. She says, "I can't complain about the lack of new treatments if I'm not willing to make the effort help find new ones!" Allison enjoys the friendships she has developed with the Stanford research team. She sees more clinical trials in her future, as well as another national cheerleading competition before she heads to college in two years—hopefully in Southern California.



istry database, and is involved in the design and initiation of the CF.DOC trial.

Behind the scenes, a host of important people support Stanford's clinical research. Research pharmacist "Marty" Hamilton oversees drug dosing and formulation to ensure all study pharmaceuticals are carefully for-

mulated with risk factors clearly identified. Research administrator Diane Baxter is pivotal in supporting the many administrative requirements of a clinical research program. The nurses in the GCRC care for subjects who stay more than a few hours, following often complicated protocols and attending to subject and family needs.

Center physicians Rick Moss, Noreen Henig, Carol Conrad, Terry Robinson & Laurie Witcoff actively participate in the protocol development, exams and procedures, and analysis of results. Offsite, physicians from other CF Centers and academic medical centers monitor all trials through the TDN and the Data Safety Monitoring Board, an independent review board with the charge of ensuring the safety of trial subjects. They review all reported side effects and have the authority to place a trial on hold. Stanford's Institutional Review Board provides internal oversight through its review and approval of all protocols involving human subjects.

In summary, all participants in the clinical trials process are committed to ensuring a safe environment for study subjects. We look forward to introducing you to our team and having you share first hand in our quest to understand and improve the lives of people with CF.

GROWING PROBLEM OF UNAUTHORIZED GENERIC ENZYMES

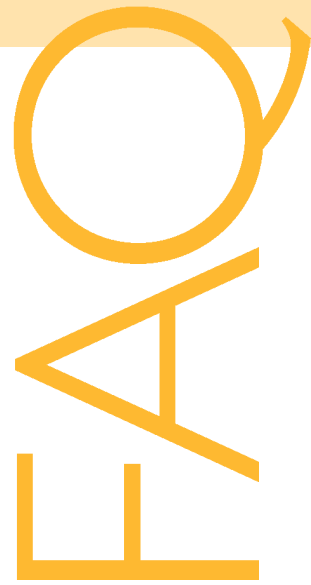
CF Centers across the country are reporting a rise in unauthorized substitutions by pharmacies of generic enzymes for FDA-approved brand name enzymes. Unlike many drugs, generic enzymes do not use the same formulation as tested and approved enzymes since some formulations were developed before the Federal Food, Drug and Cosmetic Act of 1938. These drugs have significantly different formulations and their bioequivalency to tested and approved enzymes varies widely. Efficacy in persons with CF is often limited, and complications resulting from certain formulations can be serious. According to the FDA's Office of Generic Drugs, none of the companies making generic enzymes have received FDA approval to sell these products, and none is AB-rated in the FDA's "Orange Book", the industry standard for generic equivalency. New FDA rules eventually will require all of these products to be tested, but in the meantime some companies continue to market untested products. Many insurance companies do not understand the problems associated with generic enzyme products, only noting the significant cost savings of their use. It is important to monitor the type of enzyme received from the pharmacy and report any problems to your CF center physician or nutritionist if the enzymes do not work properly.

Pancreatic enzyme supplements are required by more than 90% of persons with CF. They are broken down by stomach acid, and if introduced into the stomach without an enteric coating, they will degrade in the stomach before they reach the duodenum where fat is absorbed. People with CF rely on the predictability of a known type and dose of enzyme, and variations that affect the amount of enzymes in a preparation can alter therapeutic benefits. Many of the products produced before 1938 (and still in use today) have been found to be overfilled by more than 50% since there are no upper and lower limits to lipase (enzyme active ingredient) content, unlike FDA-approved enzymes. Product variations can include dose, resistance to acid degradation and optimal pH for product release.

HOW TO IDENTIFY GENERIC ENZYMES

You should know what brand of enzymes has been prescribed and be sure that is what you receive. Examine the bottles and pills upon receipt of a new prescription to verify that they have a recognizable brand name—Creon, Pancrease, and Ultrase. If they don't match your last prescription, ask your coordinator or physician for a prescription that clearly states "No Substitution". Let your pharmacist and physician know when a substitution has occurred. CFF executive vice president for medical affairs Preston Campbell, M.D. is forwarding reports of treatment failures associated with enzyme substitutions to the FDA. Good nutrition is essential to maintaining good health, and in most persons with CF, effective pancreatic enzymes are life-sustaining.

In each issue we will be addressing a few frequently asked questions from our Center. Please feel free to submit questions for future issues to our nurse coordinators or Judy Kirby at 650-724-3474.



In 1999 Stanford became a member of the CFF Therapeutics Development Network, a network of premier academic CF centers designated to lead and participate in early phase clinical trials to test and develop new treatments. Today our research team is busier than ever with many new and exciting clinical trials focused on improving treatments for CF. We need your help! The following answers may help you decide to become a study participant.

What is an informed consent?

Informed consent is a process of questions and answers that begins with our

initial contact and continues throughout a study. It is also a document that you sign stating that you have been informed about the study or trial and that you freely agree to participate. The consent contains the following information: purpose of the trial; procedures to be performed; number of visits; risks associated with the study; who to contact with questions; and, your rights as a study participant.

How long will my participation last?

Trials vary from a few hours in a single day to several visits over several months. Some studies can be done while you are hospitalized or having another procedure.

Is there always a benefit to participating in a clinical trial?

There may not be a direct clinical benefit to each study participant, however there is always a benefit to increasing our knowledge and contributing to research and future treatments. Many trials involve use of a placebo drug to some patients, and because our center focuses on earlier stage trials, we often do not know if there will be a benefit to a participant. Also, subjects are randomly assigned to groups (study

drug vs. placebo/inactive agent), with the exact sequence for assignment specified in the informed consent. Most often, neither the subject nor the research team knows who receives the study drug. However, even studies that do not find benefit help us eliminate unsafe or unhelpful treatment options and refocus research into more promising areas.

What happens if I get sick while doing a study?

Contact your study coordinator immediately. A coordinator is on call 24 hours a day and she will direct your care through the research team. Your health and well-being are our primary concerns. If the research team believes that your health is being compromised by the study we will withdraw you. However we will ask you to return for a final study visit so that we can assess your symptoms and health.

In general, what procedures can I anticipate, who will I see & what am I expected to do?

Most often you will have your vital signs taken (heart rate, respiratory rate, height, weight, temperature and pulse oximetry check), a physical exam, blood work and spirometry, and you will be seen by one of our study coordinators. Most trial visits take place in the clinic as outpatients, although some take place in the university's General Clinical Research Center at Stanford Hospital. You will need to arrive on time for all visits, comply with study procedures, and notify our staff of changes in your health and routine medications as soon as possible.

May I drop out of a study after I enroll?

Yes, you can always drop out of a study but the team will ask why you want to leave. If you don't think you can complete a study, please do not enroll since the enrollment and study management process is costly, time-consuming and depends on having very specific numbers of participants.

Do I get paid for participation?

Most trials reimburse you for your time and inconvenience although each study is different. This information is clearly stated in the informed consent.

Do I have to be followed by a Stanford CF physicians to be in your trials?

NO!!! We welcome any and all people with CF into our trials, and want to increase the number of participants so that we can expand the number of trials and speed with which new drugs and treatments are tested.

Who do I contact if I want to participate?

Call one of the study coordinators: Zoe Davies (650) 498-5315; Colleen Dunn (650) 736-0388; or Janie Perez (650) 723-5193. Each trial has strict enrollment criteria and they will know which ones are appropriate.

We need your help to reach our goal of better treatments and a cure. You ask: "Why me?" We reply: "Why not you?" Together we will seek the cure!



NACFC HIGHLIGHTS

The 2002 North American CF Conference in New Orleans in October brought news of improved clinical treatments, promising basic and clinical research and greater understanding of CF. Stanford physicians featured prominently in the breakthrough news. The following are the top stories our team wants to share.

Positive Results in Phase II Gene Therapy Trials

Stanford CF Center Director and Principal Investigator Richard Moss reported positive results from the multicenter Phase II clinical trial of Targeted Genetics' tgAAVCF cystic fibrosis gene therapy. 37 people with CF at 8 sites across the US received 3 monthly inhaled doses of drug or placebo and were examined at 30,60,90 and 150 days. The trial was the first multidose gene therapy trial for CF, and it was the first and so far only CF gene vector to show that the therapy is safe and well-tolerated after repeated doses. Furthermore, it was the first CF gene therapy trial ever to show statistically significant improvement in patients' pulmonary function after 30 days. No significant side effects were reported. The trial was funded by the NIH, CFF, Targeted Genetics, the Berger-Raynolds Fund and the Ross Mosier Classic.

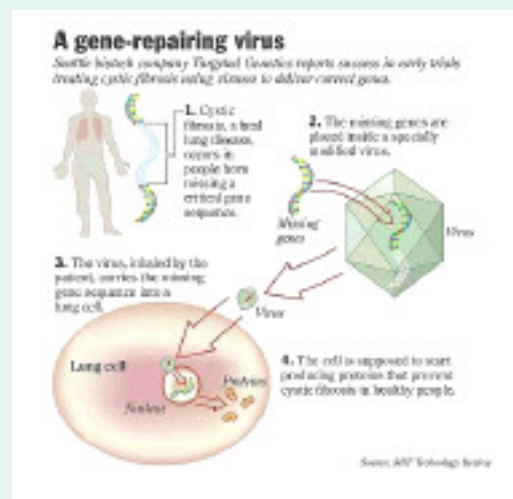
The trial found statistical improvement in FEV1 at 30 days, although the improvement was not sustained at 150 days. Levels of IL-8, a cytokine strongly associated with origin of lung inflammation in CF, were lower in tgAAVCF-treated patients, with statistical significance at 14 days. Excellent gene transfer was observed in treated patients. Samples of lung cells taken from 8 of the patients showed a surprisingly large number sported the repair gene even 60 days after treatment. "We found between 30 and 100 copies of the gene per cell, which is very encouraging," said Dr. Moss. The researchers were unable to confirm, however, whether any of the cells were actually making the protein. In vitro research suggests that only about 5% of lung cells need to make the channel protein in order to slow or block the progression of CF. AAV neutralizing antibody response occurred both systemically and locally, a factor which could diminish benefits. "The fact that we were able to increase pulmonary function, even transiently, is the first indication of any kind that gene therapy can work in cystic fibrosis," said Dr. Moss. "Most important, in contrast to the well-publicized safety issues with other gene therapy trials, our studies with this vector over the last 5 years have not raised any safety concerns."

Dr. Moss says complete analysis of data from this study, including results of CAT scan lung imaging, is nearly complete. The next study focusing on efficacy in a large number of patients is being refined with enrollment planned for early 2003 at up to 15 TDN sites.

CFF Recommends Monitoring Vitamin D

A CFF Consensus Conference on Bone Health underscores the importance of monitoring Vitamin D levels in persons with CF. Vitamin D increases calcium absorption, an important mineral due to the high incidence of osteoporosis and bone fractures associated with CF. 10-40% of persons with CF demonstrate Vitamin D deficiency. Even with optimal enzyme therapy, there is increased risk due to pancreatic insufficiency and poor absorption of fat and fat-soluble vitamins such as Vitamin D. Prolonged deficiency can lead to osteoporosis and delayed tooth eruption.

The conference recommends the following vitamin D supplementation for all persons with CF:



- Supplementation with 400 IU (International Units) per day for persons aged 0-1 year of age.

- Supplementation with 800 IU per day for persons aged one year and older.

- Sun exposure of 5 minutes three times per week under optimal conditions. Sunlight (ultraviolet band) aids in the body's conversion of a precursor substance to active Vitamin D in the skin. Skin thickness, sunscreen, air pollution, latitude and time of day and year affect the conversion.

- Annual blood test, with more frequent monitoring if levels fall below 30 ng/ml.

Sources of Vitamin D include fatty fish such as salmon and tuna, cod liver oil, and vitamin fortified foods such as milk, grain products and infant foods. Excessive doses can be toxic thus it is important to consult with your physician or our nutritionist Julie Matel for dosing guidelines.

Zithromax Trial Finds Significant Clinical Benefits

A large clinical trial conducted by the CFF Therapeutics Development Network found that the antibiotic azithromycin, marketed as Zithromax, improves lung function in persons with CF who are infected with Pseudomonas aeruginosa (PA). The controlled, double-blind trial showed that subjects taking the drug for 24 weeks experienced 1) an average 6% improvement in lung function (FEV1); 2) a nearly 50% decrease in hospital days for exacerbations; and 3) weight gain. Mild side effects experienced by some patients included nausea, diarrhea and wheezing. The trial was conducted in 23 CF centers.

Zithromax has been used as an antibiotic for more than ten years, although it is not known for its activity against PA. Its impact in CF lungs may be on the slimy mucoid coat protecting PA in the lungs and/or the inflammatory process. Future studies will assess the mechanism of action, long-term benefits and risks of continuous therapy.

The recommended dosage is a simple addition to the medical routine: 250 or 500 mg (based on weight) three times a week. Because the drug is already FDA approved, the trials results are immediately available to the CF community. "This discovery addresses the immediate need of treating lung infections in people with CF," said Lisa Saiman of Columbia University, co-principal investigator. "Because most people with CF experience a decline in their pulmonary function each year, we are extremely encouraged by the 6% improvement seen in this trial." This type of trial, identifying an effective treatment with an FDA-approved drug, is an important outcome of CFF research funding, since published, well-executed studies provide the evidence insurers want to authorize routine use of the drug. Although many physicians have used Zithromax, some experienced difficulty in getting the drug paid for because it was an "off-label" use. Contraindications are few but include allergies to macrolide-related antibiotics, liver disease, pregnancy and non-tuberculosis Mycobacterium.



NEW CF COOKBOOK: FOR THE WHOLE FAMILY!

Kids Cra ve the Darndest Things—and Grown-Ups too! is not your typical high calorie CF cookbook. Center nutritionist Julie Matel and research associate Judy Kirby set out to develop a book of recipes that could be modified, on the spot, for everyone, not just those with CF. In the process, they learned why families are challenged to prepare high calorie meals for members with CF without everyone else gaining unneeded weight! With the support of Digestive Care, Inc. they produced a book with tips on how to alter ingredients to raise or lower fat and calorie counts. Not all recipes were altered if taste or texture were compromised. The book includes calorie counts and an ingredient comparison and substitution list that can be used in other recipes, as well as sample menus to accommodate high and low calorie needs at the same table. The book was the joint effort of CF Center staff and Digestive Care, with recipes donated by patients and families from around the country. Proceeds from the book will benefit the Stanford CF Center research program.

To order your copy, please send your name and address along with the suggested donation of \$10.00 made payable to Lucile Packard Children's Hospital (LPCH) to the following address:

CF Center Cookbook
C/o Judy Kirby
LPCH Stanford CF Center
701 Welch Rd. Suite 3328
Palo Alto, CA 94304

recipe or food picture?

STANFORD CF IN THE NEWS

The CFF renewed Stanford's designation as one of its Therapeutic Development Network (TDN) centers. Since designation in 1999, Stanford has played an increasing role in TDN trial development, management and participation. Our Center is proud to have among the largest number of trials and study participant rates, thanks to our enthusiastic team and supportive CF community. Dr. Richard Moss was recently named Chair of the TDN Protocol Review Committee, the group that oversees the design and selection of study protocols. Dr. Moss also will be giving invited lectures on CF topics at medical meetings in Miami, New York, Washington and Europe in 2003.

The Thrasher Research Fund awarded a grant to David Bergman, M.D. and Richard Moss to evaluate an interactive Chronic Illness Program in children and adolescents with CF. This study builds on the CF.Doc pilot study that is evaluating use of the internet as a care management tool. The new program will provide:

- Secure consultation and messaging between patients and providers
- Individualized webpage with a personal health record, treatment goals and treatment plan
- Clinical care module for online monitoring of key health indicators, completion of health surveys and continuous improvement of treatment plan
- Virtual home visits for routine health assessment and follow-up care
- Health care information from other internet sites and the Stanford CF Center

The primary aim of the study will be to improve the nutritional status of persons with CF who are at risk for growth failure.

LPCH nursing education is offering a Continuing Education Program for health care providers (1 unit) on "Failure to Thrive" on February 4 at 7:30am and February 6 at 2:00pm in the 3 South Dayroom.

Join us in celebrating the November birth of Rebecca Sidney Henig. Dr. Henig will be returning to work in March.

We are actively recruiting subjects for the following trials:

NEW TRIALS

- BILL Amelubant study to investigate the safety and efficacy of 24 weeks of oral treatment in persons with CF. The medication may reduce the lung inflammatory response to infection (ages 6 and above).
- INS37217 Inhalation Solution (Inspire Pharmaceuticals) compared to placebo administered 3 times daily over 28 days (ages 10 to 50).

ONGOING TRIALS

- CF.Doc internet pilot project, an internet model of clinical care for pediatric and adult patients of Stanford's CF Center..
- Infant and toddler pulmonary function testing (children ages 6 months up to 40 pounds and 30 inches height).
- Concentrated TOBI: Comparison of safety and delivery time of a concentrated Tobramycin Solution for Inhalation in infants and children with CF, ages 6 months to 12 years.....

MARCH 8: 3RD ANNUAL LPCH CF EDUCATION DAY

Saturday March 8, from 10am to 3pm, will be the second annual CF Education Day at LPCH. Featured speakers and topics this year include:

INVITED SPEAKERS:

Denise Angst, D.N.Sc., a national leader on treatment adherence research, will discuss factors affecting compliance with medical treatment in CF.

Beth Sufian, Esquire: an adult with CF who specializes in legal issues facing people with CF and other disabling conditions.

STANFORD SPEAKERS:

Jose Maldonado, M.D., Department of Psychiatry: on coping with CF and depression.

Gabriel Garcia, M.D., Hepatologist: GI-related issues: DIOS and Reflux in CF.

Julie Matel, RD, Center Dietitian on nutrition.

Zoe Davies, PNP: An update on CF gene therapy.

Carol Conrad, M.D., Pediatric Pulmonary: Azithromycin use in CF.

Colleen Dunn, RCP: Current and upcoming clinical trials at Stanford.

INFECTION CONTROL PROTOCOLS

Persons with CF will be required to wear a mask at the conference. Persons who have cultured Methicillin Resistant Staph Aureus (MRSA), Burkholderia Cepacia or who are currently culturing a bacteria resistant to all antibiotics should not attend. If you have any questions about your status, please call and ask for this to be checked when you register.

PLEASE CALL TO REGISTER AS SOON AS POSSIBLE

To register for the conference call 650-723-9816. There is no cost to attend, however registration is required. A continental breakfast will be served from 9:30—10:00am, and a catered lunch will be served to all attendees.

Active Research Recruitments

- TheraCLEC Total: An open-label safety and tolerability Study of Oral TheraCLEC Total enzymes (requiring two 5 day in-patient admissions) in CF patients ages 13 to 45 with pancreatic insufficiency secondary to CF.
- Cystic Fibrosis Once Daily Aminoglycoside Collaborative Trial (CFODACT).
- Standardization of the Measurement of the Nasal Membrane Transepithelial Potential Difference.
- Diabetes Therapy to Improve Body Mass Index and Pulmonary Function.
- Hi-D FACS with CF blood & lung leukocytes of chronic oxidative stress in CF (cell samples needed).
- Health Buddy telephonic monitoring and health education program.
- Topical aminoglycosides: Study of topical aminoglycosides to activate CF genes in persons with CF who possess premature stop codon mutations in the CFTR gene. (Also seeking control subjects with CF who have two identified CFTR mutations, neither of which is a premature stop mutation). Open to children over age 6 and adults.
- Duration of Pseudomonas Aeruginosa eradication by TOBI in children under age 6.
- BIIL study to determine the safety and tolerance of repeated doses of a previously tested once daily medication when given every day for 15 days. The medication is thought to reduce the lung inflammatory response to infection. Open to children over age 6 and adults.

Please consider participating in our research efforts since it is through the efforts of all of us that better treatments will become available. Ask your physician or call our research staff if you are interested in learning more about participation.