Clinical Research Updates from NACFC

The North American Cystic Fibrosis Conference, held in October of 2009, brought plenty of hot CF news from chilly Minneapolis! It's hard to do justice to 3 days full of presentations on countless CF topics. However, here are a few of the highlights that are most pertinent to patients looking forward to new treatments and approaches to care!

Showcase: New Antibiotics

Many promising new inhaled antibiotics have recently begun development and testing in CF patients. These medications should provide important new weapons to fight infections, particularly in patients with established lung disease. Importantly, great attention is being given to the significant burden that inhaled therapies have on the lives of CF patients. Improved methods of delivery with shorter treatment times are a universal theme!

Arikace™: In the same class of drug as tobramycin, amikacin (the antibiotic component in Arikace™) has a similar spectrum of activity against CF bacteria – including pseudomonas. Uniquely, the amikacin molecules are packaged in lipid (fat) carriers that may improve the ability of the drug to penetrate into the mucus layers that surround bacteria in the CF lung. Also, in this formulation, the drug may work in the lung for longer periods of time. As a result, this once a day treatment (10-12 minutes to inhale it via an eFlow nebulizer) led to significant improvements in lung function when given for 28 days in this phase 2 study.

Dry Powder Tobramycin (TIP): Tobramycin packed into a dry powder inhaler (5-6 minutes to inhale) has now been compared to placebo in a recently completed phase 3 study. Like it's predecessor, tobramycin solution (TOBI®), TIP improved lung function when given in monthly on/off cycles. A study comparing the effectiveness of TIP and TOBI is now underway.

MP-376: This formulation of inhaled levafloxacin is now being tested, and in a phase 2 study demonstrated improved lung function when given once or twice a day with an eFlow nebulizer. Importantly, the twice a day group did appear to improve more than the once a day group.

AZLI: Inhaled aztreonam (AZLI) has undergone extensive phase 3 testing in the US and abroad, with positive published results that were reviewed at the NACFC. AZLI is delivered via an eFlow nebulizer three times daily, but only takes 2-3 minutes to deliver each dose. Importantly, approval for AZLI has now been granted in Europe, Canada, and Australia. Review in the US by the FDA continues.

Get Involved!

The adult and pediatric CF groups at UNC have contributed to some of the multi-center studies described above, and continue to be heavily involved in both single and multi-center studies focused on improving our understanding and treatment of CF. Currently, many individual studies are underway, and our excitement for the progress being made has never been higher! Of course, none of this research can be done without the contribution of your time and energy, and we are very grateful for all that our patients have already done. To learn more about how to participate in ongoing studies, please call our clinical research office: 919-966-9198. To learn more about CF clinical trials, a wealth of information is also available at the CF Foundation's website: (http://www.cff.org/research/ClinicalResearch/).

UNC CYSTIC FIBROSIS CENTER

Winter 2009

Quality Improvement: Targeting Pulmonary Exacerbations

Pulmonary exacerbations often lead to the progressive loss of lung function and gradual lung destruction over time. Their frequency is also associated with worse quality of life and shortened survival. The UNC CF Center has been particularly focused on better ways to treat, detect and prevent these illness episodes as one way of improving the quality and length of the lives of our patients. Almost a year ago, using a grant from the Cystic Fibrosis Foundation, we started new programs to improve our quality of exacerbation care, both inside and outside of the hospital.
Here is an update…

In the Clinic

Ideally, we would love to prevent all pulmonary exacerbations! Faithfully adhering to your airway clearance and exercise regimen is extremely important, as is the appropriate prescription and regular use of maintenance medications (e.g. hypertonic saline, Pulmozyme, azithromycin, inhaled antibiotics). However, exposure to respiratory viruses and other events out of your control can still trigger exacerbations. When this happens, our goal is to *detect the onset of the illness as soon as possible*, so that intensified treatments can be used to try to prevent more serious loss of lung function and illness symptoms. Hopefully, early detection can also save you a trip to the hospital or need to undergo a course of IV antibiotics at home.
So how can we achieve this? We have instituted a home monitoring program that includes the use of a hand-held *spirometer* and a *log-book* where respiratory symptoms and weight are tracked regularly. Instructions on when and where to call the CF Center is also included. Week to week assessments of your lung function, rather than every 3 months in clinic, certainly allows you and our team to be more aware of your lung health. The regular use of these tools may allow you to keep closer tabs on your disease, and to detect when something is going wrong earlier. These tools will also help you to track your improvement after new therapies are prescribed (e.g. antibiotics). To date, more than 80 adult CF patients have joined this exciting program.

If you would like to participate in this home spirometer program, please let Kathy or your CF doctor know so we can tell you more!
If you already have a spirometer and notebook, be on the lookout for a survey from our group. Your answers to these questions are very important, and are needed for us to learn how this program is helping you, and how it can be improved. Keep up the good work!

In the Hospital

Hospitalization for a pulmonary exacerbation is always a major event in patients' lives. We strive to make the most out of these hospital stays by giving you well

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Inside this issue:

Important Flu Tips — Seasonal and H1N1

This flu season offers special challenges to the CF community. Supply of the seasonal influenza and H1N1 influenza vaccines has been limited both at UNC and in local communities. This website may help identify places near you that have vaccines in stock:

http://www.flu.gov/whereyoulive/index.html

This year, you should receive 2 separate vaccinations—one for seasonal flu, and one for H1N1 flu. These shots can be given to you on the same day. Remember, patients with cystic fibrosis should get the seasonal and H1N1 flu shots; they should not get the nasal vaccine preparations.

During flu season, please remember these important infection control guidelines:

- Avoid contact with people who are sick with flu or viral illness. Droplets from cough and sneezing spread the influenza virus from person to person. It can also be spread by touching a surface with virus on it (like a table or utensils), then touching your nose or mouth.
- Wash hands frequently with soap and water, or with alcohol-based hand sanitizers.

- Contact us immediately (919-966-4131 for the pulmonary fellow on-call) if you experience fever greater than 100.5°, chills, dry cough, body aches, sore throat, fatigue and/or headache. Some people with H1N1 influenza may also experience nausea and diarrhea. Medications are available to help alleviate flu symptoms, but they must be started within 48 hours of the onset of symptoms.

For any questions, please contact Kathy Hohneker, RN at 919-966-7049.

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coordinated, aggressive care with the goal of restoring your health to its previous baseline. In examining our past practices, we realized that tighter coordination between nurses and therapists who administer aerosols and chest physiotherapy was needed. To achieve this, new procedures and tracking sheets were put in place. Our new standard is for a direct call from your physical therapist to nursing about 20 minutes before their arrival, to allow you to take any prescribed bronchodilators (albuterol) and hypertonic saline shortly before chest PT is administered. This should increase the effectiveness of all of your treatments. These procedures have been tracked in patient rooms for many months now, and we're happy to say that tight coordination is now the norm! The ability to provide at least 3 chest PT sessions and exercise 5 days per week is another goal we are aiming for with every admission. Finally, we are working to provide more ways to provide aid to patients who are on contact isolation using volunteer services. ***Please, let us know what else we can do to make your hospitalizations more effective and pleasant!***

The home spirometers being distributed through our QI program.

Have other ideas for our team to work on? They are welcomed and desired! We meet regularly to discuss our current projects and to develop new ideas of improving how we take care of our CF patients – and many of the best ideas come from patients. Don't hesitate to give us your thoughts!

Nutrition in the Hospital: The Meal Ticket Gets a Makeover

As part of UNC Healthcare's commitment to you, the Nutrition and Food Service department has created a new gray meal ticket tag designed specifically for Cystic Fibrosis patients. Instead of having to wait a week for meal tickets, the gray card may be used starting the day that you are admitted to the hospital until the day that you discharge. It carries a $6.25 balance that reloads each day. You keep the card and you can use it as many times a day as you want until meet your daily balance. It is redeemable at any of the 4 hospital cafes: Terrace, Corner, Overlook, and Larry's Beans as well as the new 6BT vending machines.

UNC recognizes that CF patients have high calorie needs and frequent hospitalizations; promoting access to a variety of foods is important. Remember that nutrition is part of your medical therapy for CF! Here are some tips for getting the most out of your hospital stay:

- Ask for double portions
- Request a written menu if you prefer it to the bedside ordering system
- Drink high calorie nutritional supplements (CIB Plus, Scandishake, etc)
- Order snacks. They are offered three times daily: 10am, 2pm, and with dinner
- Utilize high calorie supplemental meal list
- Use your gray meal card every day (volunteers can help)
- Contact your doctor or nurse if you want to get the CF dietician involved!

CORNER CAFE

Terrace Café

THE OVERLOOK CAFE

CF Patient Assistance

Need Help During the Holidays? Members of the CF/Pulmonary Research and Treatment Center have collected donations to help patients from our clinic who are having a difficult time affording essential items such as food, utilities, clothing and gasoline during the holiday season. Small, one-time awards may be available to assist patients with specific needs. Please contact Jennifer Pagel (Jpagel@unch.unc.edu, 919-966-7873) or Kathy Hohneker (khohnekr@med.unc.edu, 919-966-7049) ASAP+ if you would like to request assistance from this fund.

The UNC CF Patient Assistance Trust Fund: This fund was established to provide direct patient assistance to those who are having a difficult time affording food, bill payments, medications, and gasoline. If you are interested in learning more about this fund, please contact Jennifer Pagel (Jpagel@unch.unc.edu, 919-966-7873) or Kathy Hohneker (khohnekr@med.unc.edu, 919-966-7049).