

Cystic Fibrosis Center

Children's Memorial Hospital/Northwestern Memorial Hospital, Chicago, IL

News



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Where kids come first.

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Bone Health in Cystic Fibrosis: What You Should Know

By *Adrienne Prestridge, MD*

Growing evidence shows that changes in bone health occur in cystic fibrosis (CF). In 2002, the Cystic Fibrosis Foundation (CFF) published a consensus statement for the care of bone health in individuals with CF. As part of our center's ongoing commitment to providing quality care, we have adapted these guidelines in our patient care. This article will explore the current research behind the recommendations to help you understand the importance of good bone health.

Decreased strength of bones in patients with CF was first reported in 1979. While life expectancy has increased significantly since 1979, new complications have been recognized – such as fragile bones that can break easily as a result of osteopenia or osteoporosis. A mild thinning of the bones is called osteopenia and a more severe thinning is called osteoporosis. Osteoporosis can lead to fractures or broken bones, often in the spine and ribs, which can cause chest pain and difficulty breathing.

In the 2003 CFF Patient Registry, the incidence of fractures, osteopenia and osteoporosis was only 5% by early adulthood. This number is very low because the importance of routine screening for bone health was not well-recognized then. When

researchers looked more closely at select populations, up to 69% of CF patients actually had thin bones. Therefore, it is important that we focus on prevention, early recognition, and treatment of weak bones to achieve optimal bone health.

Healthy bones are created over many years, beginning in infancy and continuing through young adulthood. It is during this time that all individuals create a "bone bank". After we reach about 30 years of age, our bone bank is slowly depleted. That is why it is important to optimize our bone bank while young in order to prevent osteopenia and osteoporosis in later life. Research has shown that patients with CF have inadequate deposits into their bone bank during childhood, and increased losses during adulthood.

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Bone Health: What You Should Know

Why do patients with CF have decreased bone density or bone strength? There are many known causes that interact together to weaken the bones, and researchers are working on learning more. There are many risk factors such as:

- **Low body weight** Patients with a low body mass index (<25th percentile for children or <18.5 kg/m² for adults) have been shown to have decreased bone thickness and strength. Similarly, those below 90% of ideal body weight are considered at risk. See table 1 for a description of these nutrition parameters.
- **Decreased lung function** Research studies have shown that patients with CF with lower lung function (as measured by FEV₁) have thinner bones than those with higher FEV₁ values.
- **Chronic use of steroids** Inflammation in the lungs is common in CF and the molecules that cause the inflammation can weaken the bones. Steroids (such as prednisone or predlone) are sometimes used to reduce inflammation. Although a necessary medicine for some, chronic use of steroids (that is, more than 90 days in a year) can cause decreased absorption of calcium, increased loss of calcium in the urine, and weaker bones.
- **Delayed puberty** The hormones that increase during puberty contribute to good bone strength. Children with CF may have a delay in the onset of puberty compared to other children their age. A common cause of delayed puberty is inadequate nutrition with poor weight gain. (Other contributing factors exist, but they are not well understood.)
- **Impaired absorption of fat-soluble vitamins** Patients with CF who are pancreatic insufficient (that is, patients who take enzymes) are unable to digest and absorb fat and the fat-soluble vitamins A, D, E and K. Vitamin D and Vitamin K are important for adequate bone health. Vitamin K helps to strengthen the protein structure of bones.
- **Low Vitamin D stores or inadequate calcium intake** Vitamin D helps the body absorb calcium, an essential mineral for strong bones. Consistent with research findings, we have found many of our patients are Vitamin D deficient, despite taking CF vitamins (ADEK, Vitamax, and SourceCF). Even individuals with pancreatic sufficiency (that is, those that do not need to take enzymes) may have low Vitamin D levels. It is unclear why Vitamin D is not well absorbed.
- **Inactive lifestyle** Children who do more weight-bearing exercise were shown to have 17% stronger bones than their inactive peers.
- **Immunosuppressant drugs after transplant** Those who have had an organ transplant need to take immunosuppressant medicines to prevent their body from rejecting the new organ. These medicines, in combination with the transplant itself, have been shown to decrease bone strength up to 5%.

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Coming Soon to Illinois: Newborn Screening for Cystic Fibrosis



In the United States, it is estimated that more than ten million people carry the defective CF gene. Most carriers are unaware that they carry this gene because most carriers have no symptoms, and many carriers have no family history of CF. Newborn screening involves a blood test that indicates the possibility of a newborn having CF. It will alert a doctor to order further testing to confirm a diagnosis of CF. Testing babies at birth will result in early detection of CF and therefore early treatment.

In November 2003, the United States Center for Disease Control and the Cystic Fibrosis Foundation held a workshop to review the benefits and risks of newborn screening for CF. Discussion included a review of published research and experience of States that have implemented newborn screening for CF. This resulted in a recommendation that newborn screening for CF is justified, and that States should offer newborn screening, with careful implementation to maximize benefits to children and families.

The Cystic Fibrosis Foundation sponsored a workshop on Implementation of Newborn Screening for Cystic Fibrosis in August 2004. This workshop reviewed practical issues in implementation. The State of Illinois has convened a Subcommittee on Newborn Screening for Cystic Fibrosis, Newborn Screening Program, Illinois Department of Public Health. Dr. McColley participated in the CDC/CFF workshop and the CFF workshop. She is a member of the Illinois Subcommittee.

It is our hope that newborn screening will allow for early management by the multidisciplinary care team and result in better health for children with CF. We will keep Newsletter readers updated as the Illinois program progresses.

The Cystic Fibrosis Foundation Center Accreditation Process: Reflections from the Center Director

By Susanna A. McColley, M.D.



In May 2005, I complete my 8 year term on the CF Foundation's Center Committee, including 4 years as Committee Chair. It has been a great privilege to serve the CF community during this time. I've spoken to many of our Newsletter readers about the Committee, and

now wish to share some reflections with all of our readers.

The Cystic Fibrosis Foundation was founded 50 years ago by concerned parents. They recognized that CF could only be conquered if a network of physicians and researchers worked together with patients and families to build experience and conduct research. Several years later, CF Centers were established. In order to be accredited as a CF Center, specific personnel, facilities, and expertise had to be established. This principle has led the accreditation process ever since. There is no other chronic disease that has a similar level of organization for care providers, resources and research.

Few individuals are aware that the Cystic Fibrosis Foundation is the only nonprofit healthcare organization that accredits Care Centers through a peer-review process. Each year, CF Centers are required to apply for accreditation and funding. Applications are reviewed by the Center Committee, a group of Center Directors and Adult Program Directors from Centers throughout the United States. In addition, all Centers are site-visited by members of the Center Committee at least every five years. Accredited Centers and Affiliate Programs can be found on the Cystic Fibrosis Foundation website, www.cff.org.

CFF-accredited CF Centers must meet a number of requirements. For example, at least two physicians with expertise in CF must work at a center, and centers are required to have age-appropriate care for children and well as adults. Centers must have dietitians, social workers, and respiratory

or physical therapists, and must have regular team meetings to plan and review multi-disciplinary care. Laboratories that perform sweat testing are reviewed and inspected to assure that cystic fibrosis is properly diagnosed. Microbiology labs, which process respiratory cultures, must meet strict standards to make sure that all infections are properly recognized. Hospital and clinic facilities and infection control practices must meet specific standards. Teaching and research programs are evaluated.

The accreditation process is changing to reflect the CF Foundation's quality improvement goals. In the past, site review was mostly "structural", verifying that all the right people and facilities were available and used for patient care. The Committee is now looking at how care is delivered in Centers and how Centers are working to improve the health of their patients through structured quality improvement projects. The goal is to provide exemplary care at all Centers throughout the network.

CF Centers receive tremendous support from the CF Foundation. The CF Foundation gives Centers grants to help offset costs of multidisciplinary care. CF Centers have access to a web-based resource called "Port CF", which offers practice guidelines, quality improvement tools, patient educational resources and the Cystic Fibrosis Foundation Patient Data Registry. CF Centers also receive "Network News" every month, with updates on research and other initiatives.

I've had the privilege to visit many CF Centers throughout the United States during the past eight years. This has been a wonderful opportunity to meet other members of this unique network, to learn from other programs, to share ideas and to solve problems. I am proud to report that the CFF Center network is thriving, and is working collaboratively to fulfill the CF Foundation mission "to control and cure cystic fibrosis, and to improve the quality of life for those with the disease".

Editor's Note: Although Dr. McColley is retiring from the Center Committee, our CF program will continue to be well-represented. Dr. Manu Jain, Adult Program Director, will join the Center Committee in May.



Research News

Research activity at Children's Memorial Hospital and Northwestern University continues at a brisk pace. This article highlights 2 new clinical trials (Inspire Study and Growth Hormone Study) and reviews the progress of the *Pseudomonas* Type III Secretion Study which has been funded by the CFF for 3 more years.

The Inspire Study

Last year, our CF Center participated in a multicenter study sponsored by Inspire Pharmaceuticals, Inc. This study investigated an experimental drug designed to improve the hydration of airway secretions and facilitate mucus clearance. The study showed promising results, therefore, another clinical trial is scheduled to begin this spring to further evaluate this potential new therapy. Once again, our center has been invited to participate in this upcoming trial. A brief description follows.

A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, 28-Day Study of Denufosal Tetrasodium (INS37217) Inhalation Solution in Patients with Cystic Fibrosis Lung Disease. Cystic Fibrosis (CF) is characterized by thickened mucus secretions that lead to infection and damage to the lungs. The basic problem is related to abnormal transport of water and salt (sodium and chloride ions) across airway cells. INS37217 is an inhaled solution that may improve movement of chloride and water out of airway cells, therefore it may make airway secretions thinner and easier to cough up. INS37217 also make cilia, hair-like fibers on the airway surface, beat more frequently, which may give additional benefit in secretion clearance. This study sponsored by Inspire will investigate the

(study summaries continued on page 5)

The *Pseudomonas* Type III Secretion in Cystic Fibrosis

In 2003 our Cystic Fibrosis Center designed and launched a study to take a closer look at the bacteria in the lungs of CF patients. The key investigators of this study are Dr. Alan Hauser from the Department of Microbiology/Immunology at Northwestern University, Dr. Manu Jain, the Director of the Adult CF Program, and Dr. Susanna McColley, our CF Center Director. This research focuses on *Pseudomonas aeruginosa*, a common bacterium that grows in the lungs of about 80% of people of all ages with CF. It is a frequent cause of respiratory exacerbations and it is difficult to eradicate. Much of CF research is concentrating on strategies to treat *P. aeruginosa* infections and eliminate this organism.

A protein secretion system called "type III secretion" exists in *P. aeruginosa* cells and allows them to inject a toxin directly into the cells of the body. These secretions have been shown to be harmful in non-CF subjects, however, little is known about their role in the health of CF lungs. The aim of this study is to learn more about *P. aeruginosa* type III secretion in individuals with CF. Currently there are 175 patients with CF enrolled in this study, and over 1,690

Growth Hormone Study

Children's Memorial Hospital is also participating in a multicenter trial of growth hormone in children with cystic fibrosis and slowed growth called **A Phase II, Multicenter, Randomized, Controlled Open-Label Study of the Safety and Efficacy of Nutropin AQ® for the Treatment of Growth Restriction in Children with Cystic Fibrosis.**

Growth hormone (GH) is made by the pituitary gland located at the base of the brain. When the body does not produce enough GH, or when the body does not use GH properly, growth slows down. Nutropin AQ® (recombinant human growth hormone or rhGH) is a form of GH made in a laboratory. Nutropin AQ® is given daily by subcutaneous injection (a small needle stick into the tissue under the skin). Research studies have shown that giving Nutropin AQ® to slow-growing children with CF may improve growth. The purpose of this study is to investigate the safety and effectiveness of daily administration of Nutropin AQ® on growth and lung function in children with CF.

- Girls between the ages of 5 -12 years and boys between 5 -13 years with CF and poor growth who meet eligibility criteria may participate in this study.

Inspire Study

safety and efficacy (or health benefit) of two strengths of this investigational drug compared to placebo (solution with no drug in it). The drug or placebo is administered via a nebulizer three times per day for up to 28 days to subjects with mild to moderate CF lung disease.

- Six to eight subjects with CF (aged 8 to 50 years old) with mild to moderate lung disease who are clinically stable and able to do lung function tests will be enrolled at our site. Subjects must be on stable doses of their usual medications prior to screening. Your doctor or study coordinator can review your medical history and medications and discuss eligibility with you.
- Participation will last up to six weeks and will consist of approximately five clinic visits and two phone calls. Visits will include one screening chest x-ray, blood and urine collection for laboratory analysis, spirometry (breathing test) and administration of at least the first dose of study drug followed by observation/monitoring. The visits will last 1-2 hours, except Visit #2, which is anticipated to last about 5 hours.
- All study tests will be done at no charge to the subjects. Subjects will be reimbursed for time and travel based on study visits completed.

For more information, contact Margaret Delaney, research coordinator at 773-880-3263 or mdelaney@childrensmemorial.org.

Pseudomonas Type III

specimens have been examined.

Preliminary results of this extensive study were presented at the North American Cystic Fibrosis Conference in October 2004, and published in the Journal of Clinical Microbiology in November 2004. The secretion of type III proteins was highest in children with newly acquired *P. aeruginosa*, and decreased in those chronically infected with this organism. The lowest incidence of type III proteins was in the chronically infected adults with CF who are thought to have harbored *P. aeruginosa* for the longest period of time. In summary, the *P. aeruginosa* cells were found to gradually lose their ability to secrete type III proteins over time.

What are the implications of these findings? Although the clinical relevance of these findings is not yet known, this research may help determine whether a *P. aeruginosa* strain that secretes type III protein affects how sick the individual becomes and how it damages the lungs. The ability to test for type III secretion in the future may enable caregivers to deliver treatments that are more effective. Future research may be directed toward developing compounds that can modify type III secretion. With these possibilities in mind, the Cystic Fibrosis Foundation awarded Dr. Alan Hauser a research grant for \$239,000 to continue this important work.

The CF Center at CMH and NMH would like to thank all of the individuals who have agreed to participate in this relevant research study.

Growth Hormone Study

- 100 patients in the U.S., including approximately 5 patients from CMH, will be randomly assigned (like flipping a coin) to a treatment group that will receive Nutropin AQ® shots daily for 12 months - OR - to an observational group that will be followed in the same manner as the treatment group but will NOT receive growth hormone.
- All participants will have 9-10 outpatient visits in 18 months. Many of these visits may be combined with routine CF care visits. Screening and baseline visits followed by quarterly visits (which may be combined with routine CF care visits), and a follow up visit at 18 months. These visits may include a physical exam, blood test, x-ray, exercise test, completion of questionnaires, dietary history, and/or pulmonary function testing.
- There will be no charge for study-related procedures and study medication to subjects. Subjects will be reimbursed for time and travel for each visit completed.

For more information, please contact Cathy Powers, CCRC, research manager at (773) 880-8223.



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Bone Health: What You Should Know

How do we prevent the loss of bone strength and encourage the building of strong bones in people with CF? The goal is to achieve and maintain adequate nutrition, which is extremely important. Eat a variety of foods and include foods rich in calcium. Also, remember to take your enzymes and your vitamin supplements.

At every clinic visit, the CF team helps to ensure adequate nutrition and growth by evaluating the nutritional status. Once a year, as part of the annual blood test, Vitamin D levels will be assessed. If it is less than 30 ng/dL, a separate Vitamin D supplement will be prescribed, and the levels will then be rechecked. If you are at risk for weak bones, an x-ray test called a DEXA scan (dual x-ray absorptiometry)

will be obtained. This test is very simple – you lie on a table and a machine passes over you and scans your bones to measure its density. The results of the DEXA are compared to healthy people of the same age. This is statistically represented as a standard deviation from the average. If the score is one standard deviation less than the normal, it is called osteopenia. If the score is two standard deviations less than the normal, it is called osteoporosis.

Bone health begins in infancy and continues for a lifetime. Overall bone health is important to prevent complications such as fractures in individuals with CF. Your CF team will help to assess your bone strength and partner with you to achieve and maintain strong bones.

Microscopic changes in bone occur in osteoporosis.



Normal Bone



Thin, Weak Bone

Table 1: Calculating Body Mass Index and Ideal Body Weight for CF populations

Body Mass Index

Body mass index (BMI) is calculated from weight and height measurements and helps determine if an individual's weight is appropriate for their height. In the healthy population, BMI is most often used to identify overweight and obesity. In CF populations, where obesity is uncommon, a low BMI represents a nutrition risk factor.

Formula for calculating BMI:
$$\text{BMI} = \frac{\text{Weight in Pounds}}{\text{Height in Inches} \times \text{Height in Inches}} \times 703$$

Ideal Body Weight

Ideal body weight (IBW) refers to the weight that is optimal for an individual's height. For children ages 2-20 years, this index requires use of the 2000 NCHS/CDC growth charts. The IBW for a child whose height is at the 25th percentile is the weight at the 25th percentile for the same gender and age.

Adult IBW is calculated with the following formula:

Males: 106# for the first 5 feet of height + 6# for every inch thereafter.

Females: 100# for the first 5 feet of height + 5# for every inch thereafter.

Subtract 10% for individuals with small frames.

$$\% \text{ IBW} = \frac{\text{Actual weight}}{\text{Ideal body weight}} \times 100$$

Meet Our Staff



Adrienne Prestridge

Many of our families have already met our Associate CF Center Director, Dr. Adrienne Prestridge who joined us last summer. A Virginia native, Dr. Prestridge attended Eastern Virginia Medical School in Norfolk, VA and completed her residency at Children's Hospital of Pittsburgh. With a well-established CF Center (Dr. David Orenstein, author of *Cystic Fibrosis: a Guide for Patient and Family* as CF Center Director), her experience with CF care began during her residency training. Impressed by the great attitudes of the CF teenagers she cared for, Dr. Prestridge decided to make cystic fibrosis and pulmonary medicine her specialty.

Dr. Prestridge chose Cincinnati Children's Hospital Medical Center for her Pediatric Pulmonology Fellowship. There she was part of the hospital-wide quality improvement project known as "Pursuing Perfection", where CF was the model for chronic illness. The Cincinnati CFF Chapter recognized her involvement and commitment to CF care by naming her one of "Cincinnati's Finest". Her experiences in Cincinnati have been an asset to our own endeavors to improve CF care processes here at Children's Memorial. Dr. Prestridge is a member of our CFF Learning and Leadership Collaborative team, which is addressing bone health and CF-related diabetes.

Dr. Prestridge's professional interests include infant pulmonary function testing and interstitial lung diseases where she is involved in helping experts develop a patient registry and consensus guidelines for care. Appropriately, she is now the director of our Pulmonary Function Laboratory and Infant Pulmonary Function Program. Her every day patient care is focused on providing excellent, comprehensive and preventative care with attention to the goal of continuously improving the delivery of care.

In addition, Dr. Prestridge is the principal investigator for several upcoming clinical trials at Children's Memorial Hospital. These studies include the EPIC Observational and Clinical Studies comparing different treatments for newly acquired pseudomonas in young children with CF, Growth Hormone Safety and Efficacy in growth-stunted children with CF, and the Epidemiologic Study of Cystic Fibrosis, an ongoing observational study of the natural course of CF.

As busy as she is, Dr. Prestridge takes time to relax by walking, hiking and creating stained glass. She is friendly, approachable, and honest with a great sense of humor. We encourage our families to say hello and get to know her. She is a welcome addition to the Pulmonary Division and the CF team!



Janine Judge

Please welcome Janine Judge, CRT, the newest staff member to join our Pulmonary Function Lab. Janine is a respiratory therapist who has been working in the field since 1982 after receiving her degree from Long Medical Institute in

Phoenix, Arizona. She started her career initially as a means to pursue an interest in medicine and decided to stay in the field of respiratory care because she loves it. Her experience in respiratory care is extensive. Janine has worked as a respiratory therapist in home care as well as neonatal, pediatric, and adult intensive care units. Her accomplishments include being a Respiratory Care Director at the Public Health Services Hospital in Shiprock, New Mexico on a Navajo Indian Reservation, and at the University of Chicago, where she was a manager and helped to establish the first adult CF clinic in conjunction with their Pediatric CF clinic. In the private sector, Janine established a PFT Lab for a pulmonary physician group in Lake Forest, IL.

At Children's, in addition to performing pulmonary function testing and assisting with bronchoscopy, Janine is interested in research. She begins a training course for research coordinators at Northwestern University this spring. Our CF Center is very active in clinical research and Janine's assistance is most welcome.

Janine has talents beyond her profession. She is a jazz singer and plays several musical instruments, including the piano and guitar. She composes music and hopes to publish some of her tunes one day. She also loves animals, languages (she is fluent in Spanish and says she could "survive" in French), and traveling. Janine is still very interested in medicine and one of her future goals is to return to school and pursue a Physician Assistant degree. Meanwhile, we are happy to have her as a part of our team!



Calling All CF Families

The Children's Memorial Hospital Cystic Fibrosis Center is seeking members for its Family Advisory Board. Our goal is to find eight to ten parents whose children are of different ages, and who will represent our three sites in Lincoln Park, Westchester, and Glenbrook. Parents will be asked to serve for one year with an option to serve additional terms.

Dates and location will be decided based on preferences and availability. Interested parents should call Carolyn Heyman, RN at (773) 868-8979.

Every Little Bit Helps!

By Eileen Potter, MS, RD

Managing multiple medications and navigating the prescription plan maze can be time-consuming and challenging. Copays, deductibles, non-formulary prescription costs, vitamins and nutritional products that are not covered by insurance add up each year. There are several programs sponsored by pancreatic enzyme companies that provide vitamin and nutrition supplements at no cost to those who use their enzyme product. For more information on these and other programs, contact your CF nutritionist or nurse.



Product	Program	Benefits
Ultrase or Ultrase MT	Care First Program for 0-2 years old	Free Ultrase and ADEK liquid until your 2 nd birthday
Ultrase or Ultrase MT	Comprehensive Care Program for 2 years and older	Free ADEK, Scandishake or Scandical each month
Creon 5,10 or 20	Wee Care Program for 0-2 years old	Free Creon and Vitamax liquid until your 2 nd birthday
Creon 5, 10 or 20	Extra Helpings Program for 2 years and older	Free Vitamax, or Carnation Very High Calorie drink each month



2005 Great Strides is Around the Corner

Are you looking forward to spring? We are! Great Strides, the Cystic Fibrosis Foundation's nationwide fundraiser, will take place the weekend of May 21st. If you and your friends and family are interested, register your own team or join Team Children's as we walk to raise money for CF research. To kick-off Great Strides, our CF team will be holding a raffle at the hospital. Tony Talley from our PFT lab will again host Comics for a Cure. Look for more details by mail in the coming weeks. For more information, call Carolyn Heyman, RN, Great Strides team leader, at (773) 868-8979.



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