



TREATMENT

The advisory noted that options for treating depression in patients with coronary heart disease include cognitive behavioral therapy, physical activity such as cardiac rehabilitation and aerobic exercise, and antidepressant drugs (treatment with sertraline or citalopram, selective serotonin reuptake inhibitor antidepressants, appears to be safe soon after an acute myocardial infarction). But such intervention is not just to improve a patient's mental health, said Alexander H. Glassman, MD, chief of clinical psychopharmacology at the New York State Psychiatric Institute in New York City.

"We have evidence that the people who do not get better from their depression are at very high risk of dying," said Glassman commenting on the advisory. "The cardiologist needs to understand they need intensive medical treatment immediately."

MORE RESEARCH NEEDED

But while the advisory advocates for screening and treatment for depression, it also recognizes limits in understanding its relationship with coronary heart disease. The paper notes there is no direct evidence yet that treatment of depression improves cardiac outcomes, and that

patients may still remain at increased risk for major cardiac events and mortality even when treated for depression.

Michelle B. Riba, MD, called the advisory a good first step, but that further research and collaboration among clinicians are needed.

"Clearly, long-term studies are needed to let us understand how depression and heart disease affect each other," said Riba, associate director of the University of Michigan Depression Center in the School of Medicine in Ann Arbor. "This advisory sets up a roadmap to direct us on how to talk with each other." □

Pediatric Research Gets Boost From Web

Bridget M. Kuehn

FOR PARENTS ALREADY STRESSED from caring for a child with an illness, deciding whether to enroll their youngster in a relevant clinical trial can be a daunting task. But a new National Institutes of Health (NIH) Web site aims to make that process easier by providing parents with information about the risks and benefits of pediatric trials, the processes involved, and advice on how to assess such studies.

The Web site (<http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>), which was created by the National Heart, Lung, and Blood Institute (NHLBI) in Bethesda, Md, represents 1 development in a wider effort to ensure that therapies for young patients are rigorously assessed through clinical trials in children rather than based on data extrapolated from studies on adults.

"Children are not little adults—their bodies and their brains are still developing," said Renee R. Jenkins, MD, president of the American Academy of Pediatrics, in a statement about the Web site's launch. She explained that pediatric clinical trials are essential to understanding how medications affect developing children and adolescents.

GROWING FIELD

Three pieces of legislation passed since 1997 have contributed to a growing body of data about medication use in children. The Federal Food, Drug, and

Cosmetic Act (as amended by the 1997 Food and Drug Administration [FDA] Modernization Act), the Best Pharmaceuticals for Children Act of 2002, and the Pediatric Research Equity Act of

The screenshot shows the NHLBI website page for children and clinical studies. The URL is <http://www.nhlbi.nih.gov>. The page title is "children & CLINICAL STUDIES". The main heading is "How to Find Reliable Information". There is a video player featuring Vicki Pemberton, RNC, MS, Research Nurse. The sidebar contains several sections: "Importance of Research in Kids" with links like "Why Do Research in Children?", "Research Versus Care", "Safety and Protections", "Will My Child Benefit From the Study?", "What if I Want To Say No?", and "Minority Interests and Questions"; "Getting Started in a Study" with links like "The Research Team: Who's Who", "Questions You Should Consider Asking", "Will It Cost Me Money?", and "Do Kids Have a Say?"; "Once in a Study" with links like "Effect on the Family", "What Do Kids Say About Being in a Study?", "What if I Want to Leave the Study?", and "What Happens When the Study Ends?"; and "Resources" with links like "Rights of Families in Studies", "How to Find Reliable Information", "Terms You Should Know", and "Information About This Site". The main content area has a sub-heading "Information is knowledge. And knowledge is power." and a paragraph: "Getting educated about your child's condition and how studies work is often the first step toward making a decision. There are lots of resources out there to help you get the facts you need to make a good decision: the Internet, families with similar concerns, medical experts, support groups, patient advocates, friends and family members as well as others." Below this is a quote: "The greater is a power to know, the greater is a power. You search for more information, you..."

At a new National Institutes of Health Web site, parents can read about pediatric clinical trials and watch first-person accounts of clinicians, parents, and youths involved in trials.



2003 created new requirements and incentives for pharmaceutical companies marketing drugs that are likely to be used in children.

Another recent development is the pending NIH launch of a very large prospective study that will eventually include more than 100 000 children who will be tracked from before birth into early adulthood. This study is expected to contribute greatly to the understanding of children's development and how various environmental and other factors contribute to the development of disease. The study, described by its director, Peter Scheidt, MD, MPH, as an effort of historic proportions, will have a budget similar in magnitude to the Human Genome Project and take twice as long to complete.

The study, which Scheidt said will officially launch in July 2010, has faced funding problems and delays in the past. But an \$110.9 million appropriation from Congress has allowed the project to expand to include 36 study centers overseeing 72 study sites. Four more centers are yet to be added, and the study will eventually encompass

more than 100 sites. A few sites will begin recruiting pregnant women in the coming months and work to refine the study design will continue.

PARENT RESOURCE

Although supportive legislation and wide recognition of the need for research in children have raised the profile of pediatric research among researchers and pharmaceutical companies, it can be difficult to recruit families for such trials. In their work with parents to enroll infants and young children in various clinical trials conducted by the NIH's Pediatric Heart Network, Victoria Pemberton, RNC, a clinical trials specialist at the NHLBI, and her colleague Gail D. Pearson, MD, ScD, chief of the heart development and structural diseases branch of the NHLBI, have found that parents may be apprehensive and may know little about clinical research.

Even if 1 parent is interested in enrolling his or her child in a trial, other family members may be skeptical, Pearson said. Yet there are few resources available to provide families with information about clinical trials, their

risks and benefits, and how to determine whether to enroll a child.

To address this issue, Pemberton and Pearson collaborated with the New England Research Institute's communications division to help create a video and Web site that provides families with comprehensive information about pediatric clinical trials, including information about why pediatric clinical trials are important, what happens during a clinical trial, and what questions parents should ask if they are invited to enroll their child in a trial. The site also features brief videos with first-person accounts from adolescents who have participated in clinical trials, from parents who have enrolled their children in trials, as well as from clinical researchers.

Pemberton said the site also may be useful to clinicians, noting that many clinicians may be unfamiliar with clinical trial protocols and their ambivalence may steer parents away from participating. Additionally, the materials, which are free for public use, may be used by trialists to augment the consent process. □

Food Allergies Becoming More Common

Bridget M. Kuehn

THE NUMBER OF US CHILDREN WITH food allergies has grown by 18% in the past decade, according to a report by the national Centers for Disease Control and Prevention (CDC).

About 3 million US children and adolescents—nearly 4% of this age group—were reported to have a food or digestive allergy in 2007 compared with 2.3 million (3.3%) in 1997, according to data from the National Health Interview Survey, a national survey of the parents of 9500 children. These data, as well as data from the National Hospital Discharge Survey, were included in a report published by the CDC in October (<http://www.cdc.gov/nchs/data/databriefs/db10.htm#Data>).

The vast majority of food allergies (90%) are triggered by 8 foods: milk, eggs, peanuts, tree nuts, fish, shellfish, soy, and wheat. Adults are less likely to be affected because many children eventually grow out of food allergies, according to the CDC.

These findings are particularly important because asthma is at least twice as likely to occur in children who have a food allergy as in those without this condition. In 2007, for example, 29% of children with a food allergy also had asthma compared with 12% of children with no food allergy, according to the report. Children who have both a food allergy and asthma may be more likely to have an anaphylactic reaction to food and, as such, are at greater risk of death.

Children with food allergies also are more likely to have other types of allergic conditions. About 27% of children with a food allergy also reportedly had eczema compared with about 8% of children without a food allergy. Additionally, respiratory allergies are more commonly reported in children with a food allergy (30%) than in children without a food allergy (9%).

The number of children hospitalized following an allergic reaction to food also has increased substantially. Between 1998 and 2000, 2615 children and adolescents were admitted on average for such a reaction and subsequently discharged each year vs an average of 9537 between 2004 and 2006, according to data from the National Hospital Discharge Survey. □