

Sent: Wednesday, May 20, 2009 3:23 PM

To: OS OPHS CFSAC (HHS/OPHS)

Subject: CFSAC testimony -CDCCFS Research Program: Input Strategic Research Plan

TESTIMONY PRESENTED TO THE
U.S. DEPT. OF HEALTH AND HUMAN SERVICES CHRONIC FATIGUE
SYNDROME
ADVISORY COMMITTEE

CDC CFS Research Program: Input on Strategic Research Plan

May 28, 2009

Submitted by Jill McLaughlin

I have been involved in ME/ CFS advocacy for nearly a decade. First and foremost as a parent and caregiver, but I have also worked with patient organizations, participated in several Department of Health and Human Services (OHHS) committee meetings, attended and participated in related conferences, and currently I am on a committee of the International Association for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (IACFS /ME) .

During that time, CDC has done virtually nothing to study or address ME (or what is being called CFS, commonly referred to as ME/CFS) in children, or to promote physician, school or public education and awareness of the illness or to even acknowledge that it exists. When the CDC whistleblower scandal regarding the CDC misuse of funds broke several years ago, a large study on children was summarily dropped, ostensibly due to lack of funds. When the money was restored, the study on children was never resumed.

The medical community and the public look to the federal health agencies for information and guidance, but there has been very little leadership in this area.

CDC *did* launch an expensive national campaign for chronic fatigue syndrome. for education and awareness. The message was "Get Informed, Get Diagnosed, and Get Help." The general reaction to the slogan was: about what -fatigue and unwellness, by whom, and how? The erroneous assumption being that there are health care providers capable of diagnosing and treating it. According to the CDC only about 15% of CFS patients in the U.S. have been diagnosed. What was suggested did not exist and was next to impossible with the current physician mindset and available research.

This campaign was a waste of time and money (except for the CFIDS Association as contract recipients). Marketing and PR are no substitute for science and physician education.

The illness is housed and studied in the National Center for Zoonotic, Vector-Borne, and Enteric Diseases (ZVED), yet most of the CDC CFS research is stress related.

A review of the scientific literature on the relationship between stress and disease, published in JAMA, found that stress is a contributing factor in a wide range of inflammatory disease. It is hardly unique to CFS, yet CDC studies do not consider these findings or use adequate study controls.

CDC research focuses on a few narrow, select gene studies involving HPA axis as it relates to PTSD or stress disorders, giving the impression that the illness is psychosomatic.

Consequently, many doctors still do not believe in CFS or that it is a physical illness or that it's serious or disabling. Most doctors, particularly pediatricians, still do not know how children present with this illness or how it is diagnosed or treated.

Even intelligent parents who are told by medical professionals that there is nothing wrong with these kids and they just need tough love and to try harder may take this at face value. If the experts say it's nothing then these kids must just be faking or making it up.

While the name issue is sometimes dismissed as unimportant, trivial or "political," research done by DePaul University has shown that the name 'Chronic Fatigue Syndrome' can influence how patients are perceived and ultimately treated by medical personnel, family members, and the general public, and that the negative stigma associated with CFS may be partially due to the trivializing name. The article, "How Science Can Stigmatize:

The Case of Chronic Fatigue Syndrome" discusses how flawed scientific policies have contributed to the stigma associated with CFS and have affected research findings and clinical care.

Schools are often the most intractable, though school problems are secondary to the lack of education and awareness and sufficient backup from the medical community. Calling the illness 'chronic fatigue syndrome' implies that the child is tired rather than suffering from multiple disabling effects of brain, CNS and immune system dysfunction (as typically found in the illness that was previously known as Myalgic Encephalomyelitis or ME). In general, "fatigue" is no excuse to miss school (as in "we have sick kids with real diseases who 'try' to come to school so no excuse for the tired ones").

Absent adequate research and information, it has become too easy to assume that the illness is psychological. Patients and particularly children are being harmed by these erroneous assumptions. The overwhelming experience as well as some available research shows that pacing and living within the energy envelope is the most effective way to manage the illness and that it is harmful to push beyond the boundaries and force recovery~ Yet much of the advice on "CFS" from uninformed physicians is to the contrary.

It has become impossible to separate the medical and educational systems. School absences often become the focus and trigger suspicions of truancy or educational neglect. Yet children are often made worse by inappropriate or unrealistic educational demands and pushing too hard. It *is* abuse to send a child to school when they are ill but if the illness is not recognized by pediatricians, parents have nowhere to turn and may even be charged with neglect if they do not send them to school.

Families of ME/CFS children can face their worst nightmare at the hands of these misinformed doctors and school systems. Parents are being falsely accused of Munchausen Syndrome by Proxy, also known as Factious or Induced Illness (MSBP/FII), simply because the child has a neurological illness that is often stigmatized and misunderstood. False accusations of MSBP/FII have frequently involved social service agencies regarding ME/CFS children, with the result that the child may be removed from the home.

The Tymes Trust children's charity in the UK produced "The Forgotten Childrerri" Dossier in 2003. A survey was conducted and featured on BBC Panorama, which showed very disturbing statistics regarding the accusation rate of Munchausen Syndrome by Proxy (MSBP/FII) of parents with ME/CFS children.

Statistics at that time showed that overall accusations of Munchausen's Syndrome by Proxy affected just one in 100,000 families. Yet 7% of children from families questioned had been subject to child protection proceedings and court proceedings had either been threatened or carried out. If this is representative, it implies that seven out of every one hundred children with ME/CFS will be threatened with being taken away from their parents.

Cases of children with ME/CFS being taken into custody due to false allegations and accusations of abuse, neglect and MSBP/FII are by no means diminishing but are continuing worldwide.

Thus it was extremely disturbing that a press release was issued on a CDC funded study which identified childhood trauma, sexual abuse and emotional maltreatment as a major risk factor for the development of CFS. Yet other studies on the relationship of trauma to CFS have shown the opposite.

Apparently no consideration was given by CDC to an extensive risk factor study ("Risk factors for chronic fatigue syndrome/myalgic encephalomyelitis: a systematic scoping review of multiple predictor studies") that reported on various potential risk factors for the development of CFS. It concluded that definitive evidence that appears meaningful for clinicians is lacking.

Why was CDC studying something as vague as childhood trauma and when CDC has not looked into more obvious or compelling risk factors associated with physical or biological rather than psychosocial aspects.

For example, there is widespread agreement that a variety of infections are capable of precipitating ME/CFS (which the National Center for Zoonotic, Vector-Borne, and Enteric Diseases (ZVED) should be able to properly study). Furthermore, if an antigenic challenge by infection can precipitate ME/CFS, then it would follow that vaccines could act similarly. Lloyd et al reported that several patients linked the onset of ME/CFS to receiving a vaccination in the absence of infection.

These associations have been reported by Dr. Byron Hyde of Canada and by Dr. Charles Shepherd of the UK and were included in the CMO report (Report to the Chief Medical Officer of an independent working group to the UK National Health Service).

CDC constantly focuses on the role of stress, yet it is very stressful to have an illness that remains unrecognized and unaccepted. Research has found that the majority of CFS patients seeking medical treatment reported feelings of estrangement, and one study found that 66% of individuals with CFS felt that they were made worse by the care they received (source: Prohealth Live Chat Q&A with ME/CFS Research & Policy Leader Leonard A. Jason, PhD, August 14, 2007).

Dr. Nancy Klimas, renowned expert and past President of the International Association for CFS/ME, was quoted in the Miami Herald as saying "I've had patients who met post-traumatic stress disorder criteria.... where their trauma was their interaction with their physician around this illness. They came to a doctor with Chronic Fatigue Syndrome; they left the doctor with PTSD."

Perhaps the finding of PTSD or stress related gene expressions in ME/CFS is iatrogenic. CDC's focus on stress or related gene abnormalities may be studying the result, not the cause.

And consider how stressful it must be, particularly for sick children, who have lost much of their formative years and identity, to be dismissed, blamed, viewed as lazy, malingering or irresponsible, when nothing could be further from the truth. When in fact they generally try much harder and push well beyond what they are capable of physically and cognitively

to the detriment of their own health.

With any other illness these children would be heroes and applauded for their tenacity and efforts, with all kinds of help and support available to them and their families. Anyone facing a crisis or illness always admits they could not have managed or survived without support and understanding, yet patients with ME/CFS often have none.

As difficult as it is for adults, think of what happens to children who are not believed and forced to attend school and gym class and are literally punished for being sick. Adults may be fully disabled and do not have to work, yet children are required to attend school.

Health should come first, and children should be given sufficient time to recover before returning to school. Sustainable, manageable or even home-based education is important to meet education requirements.

These families are not only trying to fight the illness itself to care for their children but must constantly deal with all of the prejudice and misinformation surrounding it. Affected children continue to struggle for recognition of their needs, and often are dismissed or even bullied by medical and educational professionals. It is the children and families that are being abused and stressed by the failure of the systems, agencies and institutions to properly research the illness and educate those who should be helping and caring for them.

With support and concern or even basic understanding lacking, it can become overwhelming for families. Parents have to try to assume the role of doctor, nurse, teacher, psychologist and often best friend. Over time many children are never able to work and contribute financially, many cannot drive, so the burdens on families are enormous. It is not uncommon to have mothers who have ME/CFS as well as the child, or to have more than one child with it. It becomes nearly a full time job handling all of the medical, school and social/emotional issues.

Children can miss a great deal of school, often years. A UK study (Dowsett/Colby) found that ME/CFS constitutes the biggest cause of long-term sickness leading to absence from school, in both staff and pupils. It found that the scale of the problem in children is substantial, and the pattern of illness showed a clustering of cases.

Many children have not received an adequate education, have had very limited social interactions and normal childhood

and "life" experiences and become very isolated. They may very well end up having emotional problems, depression or would understandably be angry, resentful or distrustful of authorities.

These children may get so far behind and frustrated that they simply drop out of school. Many families have such traumatic experiences with schools that they literally just try to stay beneath the radar of suspicion and bide their time until the child is 16 and can drop out.

Under these circumstances, how many children with ME/CFS, or those who are not properly diagnosed or treated, have turned to drugs or alcohol, or even suicide?

Studies have looked at the profound economic impact of CFS in the adult population, but what of the future effect on these children and society? Some studies have found that children may recover in their late teens or early 20's, but even for those lucky enough to recover, many have still missed their formative years and large amounts of school, often years. These educational opportunities are completely lost with regard to public education as most school districts do not provide services beyond age 21.

For those who get sick in childhood or in their teens and do not recover, many get worse over time, unable to work or even become bedridden. And aging parents struggle and worry about what will happen to their children, as disabled adults, when they can no longer care for them.

How successful can a research program be when the real stakeholders (i.e. patients) report thusly. In the 20 years since the inception of the CDC "CFS" research program, there has been no real progress of direct benefit to patients in terms of recognition, diagnosis, treatment or basic care. The merit of the investment should be judged by the final result.

This situation must change with. The real tragedy is that with proper diagnosis and treatment, children can receive appropriate care and support even if there is no cure, and with appropriate accommodations they will be able to access the best educational opportunities possible.

Jill McLaughlin

Input for CDC's research program:

Discontinue the use of the new "empirical" definition and rebranding CFS as a "stress-related disorder."^R This definition is too non-specific, reduced to questionnaires based on a Wichita 2-day hospital stay, and excludes the most serious patients and includes patients who mainly have depression.

Adopt the Canadian Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols. A DePaul study ("Comparing the Fukuda et al. Criteria and the Canadian Case Definition for Chronic Fatigue Syndrome") found that the Canadian criteria group, in contrast to the CFS Fukuda group, had more variables that statistically significantly differentiated them from the psychiatric comparison group. The Canadian criteria selected cases with less psychiatric co-morbidity, more physical functional impairment, and more fatigue/weakness, neuropsychiatric, and neurological symptoms.

Recognize and focus research direction on known abnormalities of reduction in grey matter of the brain, mitochondrial abnormalities, channelopathies and aberrant ion transport, low natural killer cell cytotoxicity, cytokine shift from Th1 to Th2, sympathetic nervous system hyperactivity, cortisol deficiency, left ventricular dysfunction in the heart and other cardiovascular abnormalities that can have serious clinical implications. A variety of theories have been proposed to explain these findings and offer insight into the pathophysiology, including infectious agents, viruses, bacteria, tick borne infections, immune dysregulation, neuroendocrine problems, as well as neurologic abnormalities, oxidative stress and kindling.

We need clinical and laboratory-based studies of homogeneous groups of patients to produce meaningful data that can be replicated and used to provide insight into the nature and pathophysiology, not questionnaires about fatigue and "unwellness."

Expand the CDC CFS research program. One person should not have full control of any research program or budget. Then fund and award contracts to outside investigators who have proven abilities and accomplishments in targeted areas.

Remove references and links to the thoroughly flawed and discredited NICE (UK NBS National Institute for Health and Clinical Excellence) guidelines for diagnosis and management. These guidelines do not follow the neurological WHO classification and promote CBT and GET (graded exercise therapy), which has been shown to make patients worse. Pacing involves the conservation of energy, not expending more to force recovery.

The International Association for Chronic Fatigue Syndrome/Myalgic

Encephalomyelitis (IACFS/ME) has developed a case definition for Pediatric ME/CFS. The existing case definitions have been developed for adults and may not be appropriate for children. The IACFS/ME convened a working group of experts who determined that there is sufficient evidence to put forward a case definition for children and adolescents. Having a consistent and reliable case definition is of utmost importance to properly diagnose and classify patients for research in order to determine the pathophysiology, identify biomarkers and develop effective treatments.

The CDC should recognize the IACFS/ME Pediatric Case Definition and use it as the basis to develop a research program on pediatric ME/CFS with focus on determining the cause, risk factors, biomarkers and effective treatments. Since children with ME/CFS can become adults with the illness over time, the natural history must also be considered.

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